

ICAR RE-CERTIFICATION

Company name: Foss Analytical A/S

Instrument name: Fossomatic™ 7

Milk species: Cow milk

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Approved and revised by Milk Analyses Sub Committee

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Table of Contents

1.	Preface	3
2.	Principle	3
3.	Scope	3
4.	Data evaluated	3
5.	ICAR proficiency tests	4
6.	Stability	5
7.	Robustness	6
8.	Foss report on the software change log on Fossomatic™ 7	7
	8.1 Version 3.6.3 Release March 2025	7
	8.2 Version 3.6.2 Release July 2024	7
	8.3 Version 3.6.1 Release July 2023	7
	8.4 Version 3.6.0 Release October 2022	7
	8.5 Version 3.5.0 Release November 2021	7
	8.6 Version 3.3.0 Release December 2020.....	7
9.	Conclusion	7

1. Preface

Fossomatic™ 7 was fully certified by ICAR in May 2020 with the organization of a interlaboratory study.

The purpose of this report is to evaluate if the instrument, introduced on the market at the end of 2016 is still meeting the requirements of the previous granted certification after five years.

The instrument is applied in central milk testing laboratories and dairy laboratories for milk recording analysis and milk payment testing.

The data obtained in the ICAR proficiency test and from the interviewed laboratories have been used for the evaluation.

The limits reported in reference documents reported below and the above results obtained, will be considered in the evaluation.

The performances will be evaluated against criteria listed in:

- ICAR protocol “Procedure 1 of Section 12 of ICAR Guidelines – Protocols for Evaluation of Milk Analyses for ICAR Approval”, which in turn is aligned with
 - ISO 8196-3 | IDF 128-3:2009 – Milk — Definition and evaluation of the overall accuracy of alternative methods of milk analysis — Part 3: Protocol for the evaluation and validation of alternative quantitative methods of milk analysis and
 - ISO 13366-2 | IDF 148-2 Milk — Enumeration of somatic cells — Part 2: Guidance on the operation of fluoro-opto-electronic counters

2. Principle

Fossomatic™ 7 It is an automatic, dedicated fluoro-optoelectronic instrument, based on flow cytometry, used for a rapid determination of somatic cell count in raw milk. Fossomatic™ 7 can measure the total somatic cell count in fresh or preserved raw milk works at a speed of up to 600 samples/h.

3. Scope

The scope of the re-certification is total somatic cell counting in raw cow milk.

4. Data evaluated

- Nine rounds of ICAR Proficiency test from March 2021 to March 2025
- Raw data and report from Milchprüfing-Bayern (DE) 2024 on 11 Fossomatic™ 7

5. ICAR proficiency tests

The ICAR proficiency test data from March 2021 to March 2025 have been evaluated. For the purpose of re-certification, these data were used to calculate and assess the repeatability of the Fossomatic™ 7. The reproducibility has been not evaluated because is influenced by the calibration settings specific to each laboratory.

For the total somatic cell the repeatability of the Fossomatic™ 7 was found to be:

- $r = 27,21 \text{ cell} \cdot 1000/\text{ml}$
- $sr\% = 1,6$

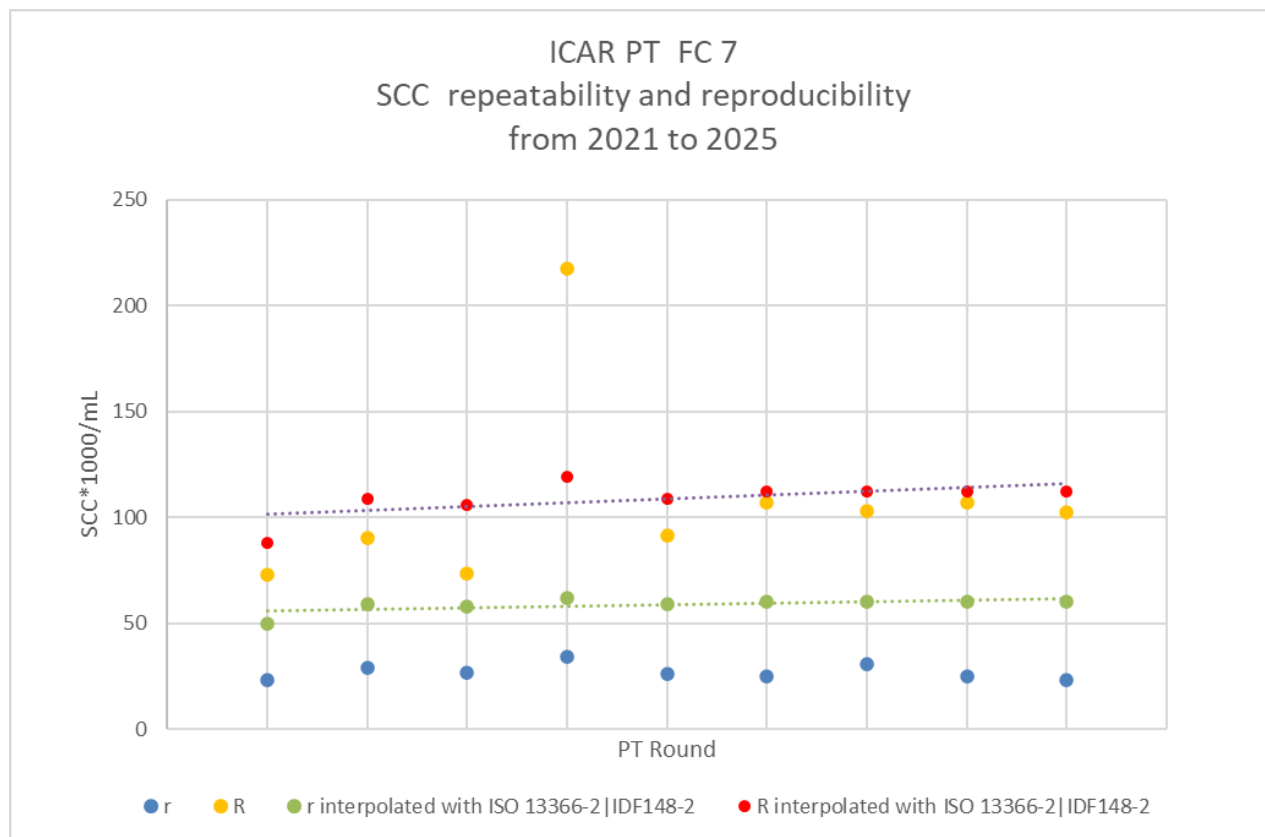
These values are below the limit defined by ISO 8196-3 | IDF 128-3, which is $sr \leq 4\%$ for the whole range

Table 1. and Figure 1. report the results of each proficiency test for Fossomatic™ 7 and its overall performance.

Table 1. ICAR PT Total Somatic cell Counting (SCC) - Summary Table

	rt0321	rt0921	rt0322	rt0922	rt0323	rt0923	rt0324	rt0924	rt0325	Overall
count	12	14	14	18	21	16	20	20	19	
n samples	120	140	140	180	210	160	200	200	190	1540
n.outliers Cochran	0	0	1	3	1	2	1	1	0	
n outliers Grubbs	0	0	1	4	0	0	2	1	4	
average	448	596	578	683	600	623	625	623	621	600
s_r^2	68,192	105,4964	90,31813	147,7407	85,4244	80,86538	120,7572	80,86538	70,50205	94,46237
s_r	8,26	10,27	9,50	12,15	9,24	8,99	10,99	8,99	8,40	9,72
s_L^2	614,800	927,814	595,1434	5892,236	987,5122	1387,501	1236,849	1387,501	1271,366	
s_R^2	682,992	1033,31	685,4615	6039,976	1072,937	1468,366	1357,606	1468,366	1341,868	1683,431
s_R	26,13	32,15	26,18	77,72	32,76	38,32	36,85	38,32	36,63	41,03
s_r_relative	1,8	1,7	1,6	1,8	1,5	1,4	1,8	1,4	1,4	1,6
sR_relative	5,8	5,4	4,5	11,4	5,5	6,1	5,9	6,1	5,9	6,8
repeatability	23,12	28,76	26,61	34,03	25,88	25,18	30,77	25,18	23,51	27,21
Reproducibility	73,18	90,01	73,31	217,61	91,72	107,29	103,17	107,29	102,57	114,88
repeatability_relative	5,2	4,8	4,6	5,0	4,3	4,0	4,9	4,0	3,8	4,5
Reproducibility_relative	16,3	15,1	12,7	31,8	15,3	17,2	16,5	17,2	16,5	17,6

Figure 1. ICAR PT Total Somatic cell Counting (SCC)



6. Stability

In 2024, Milchprüfing Bayern (DE) provided statistics on pilot sample analysis. A total of 410.093 pilot samples were examined, of which 1877 were found to be outside the specified tolerance limits for fat, protein, lactose, or urea—resulting in a deviation rate of 0,46 % for the parameter somatic cell.

Pilot samples are analyzed systematically: two are measured at the beginning and end of each batch, and also after every 45 DHI samples. The acceptance range is defined as $\pm 10\%$ for a pilot sample with a minimum concentration of 15.000 cell/ml. Both pilot samples must fall within these limits. The maximum deviation for a single pilot sample is $\pm 20\%$, with a minimum of 40.000 scc/ml. If any of the measured values fall outside the acceptance range, the analysis is automatically halted. The device operator is then required to identify and correct the source of the deviation. After corrective action, two new pilot samples must be analyzed at system start-up, and the last 45 samples must be reanalyzed to ensure instrument stability.

To evaluate Intralaboratory reproducibility, Milchprüfing Bayern (DE) provided the results of a pilot sample analyzed using 11 Fossomatic™ 7 instruments over eight different working days, from 2023 through January 2025.

Each daily session had an average working time of about 14 hours.

Each pilot sample is analyzed at intervals of 4 to 5 minutes.

A total of 7966 pilot data were received for Somatic cell Counting. These results were subjected to statistical analysis.

The standard deviation of intralaboratory reproducibility (sRintra) was calculated considering the pilot repeatability (sr) and the pilot standard deviation between instruments (sL) of eight working routine day.

Table 5. shows that the intra laboratory relative repeatability and itra-laboratory reproducibility calculated for each working session on the 11 instrument.

Both criteria are in the limit reported in the ISO 8196-3 | IDF 128-3 for a low range of concentration.

sr % FM 7=3,0 % is in the limit of $sr \% \leq 6\%$

sRintra % FM 7=3,5 % is in the limit of $sRintra \% \leq 7\%$

Table 2. Results of pilot sample on 11 instruments

		30.01.2023	13.03.2023	21.04.2023	21.05.2023	13.06.23	16/12/2024	17/12/2024	15/01/2025	mean	Limit ISO 8196-3 IDF 128-3
SCC [$1000/mL$]	mean	182	207	255	198	151	185	251	227	207	6% 7%
	s	5,2	5,3	6,4	5,4	4,7	5,3	6,4	5,7	5,58	
	s%	2,85	2,55	2,50	2,73	3,13	2,89	2,54	2,51	2,70	
	sr	5,06	8,25	6,50	5,67	5,09	5,75	6,50	6,55	6,25	
	sL _{intra}	3,768	0,000	4,439	3,640	3,066	3,474	4,419	3,318	3,52	
	sR _{intra}	6,309	8,250	7,871	6,738	5,942	6,718	7,860	7,343	7,17	
	R _{intra}	17,66	23,10	22,04	18,87	16,64	18,81	22,01	20,56	20,08	
	sr%	2,78	3,99	2,55	2,86	3,37	3,11	2,59	2,89	3,02	
	sRintra %	3,47	3,99	3,09	3,40	3,94	3,64	3,13	3,23	3,46	
	n	706	772	931	887	1192	1204	1244	1030	7966	

FossomaticTM 7 showed a very stable performance in between periodic maintenance each 3 months (appr. 450-500 $\cdot 10^3$ samples).

7. Robustness

Milchprüfing Bayern provided information on their collaboration with the manufacturer and the technical support arrangements, summarized as follows:

"In addition to the scheduled maintenance performed every three months, Foss Germany organizes two meetings per year to discuss potential technical issues and future improvements with customers.

Thanks to the pay-per-sample contract, nearly all spare parts are kept in stock at the Milchprüfing Bayern (DE) laboratory. We receive excellent technical support: if a problem arises that we cannot resolve internally, a Foss technician is available upon request.

While the system is generally robust, a few technical issues have been observed:

- *FM RSH modul: liquid sensors have to be replaced more often*
- *Flowcell and laserblock have to be readjusted more often*

Despite these issues, the FossomaticTM 7 has demonstrated very high reliability and durability over the years, both in terms of hardware performance and analytical consistency."

8. Foss report on the software change log on Fossomatic™ 7

The following information are about new or changed functionality compared to earlier versions of the Foss Integrator Software.

8.1 Version 3.6.3 Release March 2025

- Using prediction input display can cause internal error on Fossomatic 7. If the user would inspect samples selecting them in the prediction input display to see their PHA curves, Foss Integrator would crash.

8.2 Version 3.6.2 Release July 2024

- A customer lost several samples as the software did not react properly to an internal crash, instead it kept running. Fault handling was improved to prevent such situations going forward.
- Connection loss fixed.
- FMA lot settings in Spanish adjusted.

8.3 Version 3.6.1 Release July 2023

- Support for SQL 2014 and Win 7 ended

8.4 Version 3.6.0 Release October 2022

- After running the rinse job, Foss Integrator asks to put a cup under the pipette and do the job a second time. In one of the places there were errors after the job was done. This has been fixed.

8.5 Version 3.5.0 Release November 2021

- Extra suction was implemented to avoid pipette drip when instrument change mode from Stop to Standby and Standby to Stop.
- Introduced a pinch valve startup exercise. This is implemented to avoid low cell count in first sample after going from Standby to measure mode, which can be caused by slow/dozy pinch valves.
- A notification to inform customers that intercept adjustment should not be performed when doing S/I adjustment on a Fossomatic. This will assist customers getting correct and understandable results - especially on a Fossomatic 7 DC where the DSCC value is disabled or set to zero when cell count is below 50k. The new notification is applied to all Fossomatic instruments: Fossomatic 7 DC, Fossomatic 7 and Fossomatic FC.

8.6 Version 3.3.0 Release December 2020

- The warning and Error descriptions and their hints were improved to be more informative.
- The following information are about new or changed functionality compared to earlier versions of the Foss Integrator Software.

9. Conclusion

The results show that the Fossomatic™ 7 repeatability and overall intra laboratory reproducibility for total somatic cell counting are lower than limits reported in ISO 8196-3|IDF 128-3

The data provided by Milchprüfing Bayern, provided robust evidence of the instrument's stability.