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UF Commissioning Report

Customer:	CHRISTIAN INSTITUTE OF HEALTH SCIENCES & RESEARCH	Date:	12 September, 2029
Model:	UF-4000	Engineer:	JAKIR HUSSAIN MONDAL
Serial No :	11929	A.Specialist:	Jayant Kumar Samal
Date Install:	12-Sep-20	BL Date:	

1 BACKGROUND VERIFICATION

1.1 Before performing adjustments to the Urinalysis analyzer, ensure there is no background error appeared to the analyzer.

Table 1 - result of background check

Parameters	Results	Acceptable Range	Status
RBC	0.0	≤ 1.0 /uL	Pass
NL RBC	0.0	≤ 1.0 /uL	Pass
WBC	0.0	≤ 1.0 /uL	Pass
WBC Clumps	0.00	≤ 1.0 /uL	Pass
EC	0.0	≤ 1.0 /uL	Pass
Squa.EC	0	≤ 1.0 /uL	Pass
Non SEC	0	≤ 1.0 /uL	Pass
Tran EC	0	≤ 1.0 /uL	Pass
RTEC	0	≤ 1.0 /uL	Pass
CAST	0	≤ 1.0 /uL	Pass
Hy. CAST	0	≤ 1.0 /uL	Pass
Path.CAST	0	≤ 1.0 /uL	Pass
BACT	0	≤ 5.0 /uL	Pass
X'TAL	0	≤ 1.0 /uL	Pass
YLC	0	≤ 1.0 /uL	Pass
SPERM	0	≤ 1.0 /uL	Pass
MUCUS	0	≤ 1.0 /uL	Pass
SF_TC	123	≤ 3000 Count	Pass
CW_TC	43	≤ 300 Count	Pass
CB_TC	103	≤ 3000Count	Pass

Paste the Result of Background result screen

3 OPTICAL AXIS VERIFICATION

Material Used : Latex DUKE 4207A (7um) (P/N: CX472678)
Latex DUKE 4010A (1um) (P/N: 52123572)
Latex Fluorescent C47410(Marketing name: A-16500) (P/N: BP783854)

3.1 Optical Axis adjustment result must be done by executing FINE [Optical Axis Adjustment]. The results are shown here:

Table 3 - Laser Latex run results

Parameter		Latex Count Result				CV Result		
		Target	Results	Limit	Status	Results	Limit	Status
7µm SF_FSC_P	1st	150	143	± 50	Pass	1.7	< 2.8 %	Pass
	2nd		143		Pass	1.7		Pass
	3rd		143		Pass	1.7		Pass
1µm CB_FSC_P	1st					Yes	Check for single peak	Pass
	2nd					Yes		Pass
	3rd					Yes		Pass
2.5µm SF_FLH_P	1st	120	108	± 60	Pass	3.1	< 7.5 %	Pass
	2nd		108		Pass	3.1		Pass
	3rd		107		Pass	3.2		Pass
2.5µm SF_SSH_P	1st	120	102	± 60	Pass	4.8	< 7.5 %	Pass
	2nd		102		Pass	4.5		Pass
	3rd		102		Pass	4.5		Pass
2.5µm SF_DSS_P	1st	120	128	± 60	Pass	Yes	Check for single peak	Pass
	2nd		127		Pass	Yes		Pass
	3rd		128		Pass	Yes		Pass

4 SENSITIVITY ADJUSTMENT

4.1 Material Used : UF-Calibrator (P/N: CN383000)
Lot No. : UA0077
Expiry date : 16 October, 2020

4.2 UF Calibrator Assay Sheet UF Calibrator Assay Sheet

Table for UF Calibrator Assay value

Parameter	Target	Lower Range	Upper Range
Calibration Particle /uL	843.6	801.4	885.8
Conductivity ms/cm	34.9	32.8	37.0
Parameter	**Lower Range**	**Upper Range**	**Target**
SF_FSC_P	150.3	153.3	151.8
SF_FSC_W	43.2	44.2	43.7
CW_FSC_P	102.7	105.7	104.2
CB_FSC_P	163.2	166.2	164.7
SF_FLL_P	109.2	115.2	112.2
SF_FLH_P	109.2	115.2	112.2
SF_DSS_P	169.7	179.7	174.7
CW_SSH_P	108.1	114.1	111.1
CW_FLH_P	61.0	65.0	63
CW_DSS_P	21.2	23.2	22.2
CB_SSH_P	201.4	217.4	209.4
CB_FLL_P	105.5	125.5	115.5
SF_SSH_P	189.7	199.7	194.7
SF_SSL_P	189.7	199.7	194.7
CW_SSL_P	21.4	23.4	22.4
CW_FLL_P	61.0	65.0	63.0
CB_FLH_P	105.5	125.5	115.5

4.3 Sensitivity adjustment is done by executing [Sensitivity adjustment]. The results are shown here:

4.4 Go to sensitivity adjusment

Table 6 - result of sensitivity

Parameter SED (Ch)	Target	Results	Acceptable Range(±)	Status
SF_FSC_P	151.8	151.9	1.5	Pass
SF_FSC_W	43.7	44.0	0.5	Pass
CW_FSC_P	104.2	104.5	1.5	Pass
CB_FSC_P	164.7	164.8	1.5	Pass
SF_FLL_P	112.2	112.2	5.0	Pass
SF_FLH_P	112.2	111.9	3.0	Pass
SF_DSS_P	174.7	172.8	5.0	Pass
CW_SSH_P	111.1	110.4	3.0	Pass
CW_FLH_P	63.0	61.5	2.0	Pass
CW_DSS_P	22.2	21.8	1.0	Pass
CB_SSH_P	209.4	210.6	3.0	Pass
CB_FLL_P	115.5	114.0	10.0	Pass
SF_SSH_P	194.7	190.8	5.0	Pass
SF_SSL_P	194.7	192.0	3.0	Pass
CW_SSL_P	22.4	22.3	1.0	Pass
CW_FLL_P	63.0	61.8	2.0	Pass

* *Due to average of the UF Calibrator target value was been round-up to one decimal point, adjustment final result will be base on the status result*

Analyzer UF-4000
File No 1
Lot No UK0083

QC Data

Material UF-CONTROL-L
Exp Date 2020/10/12

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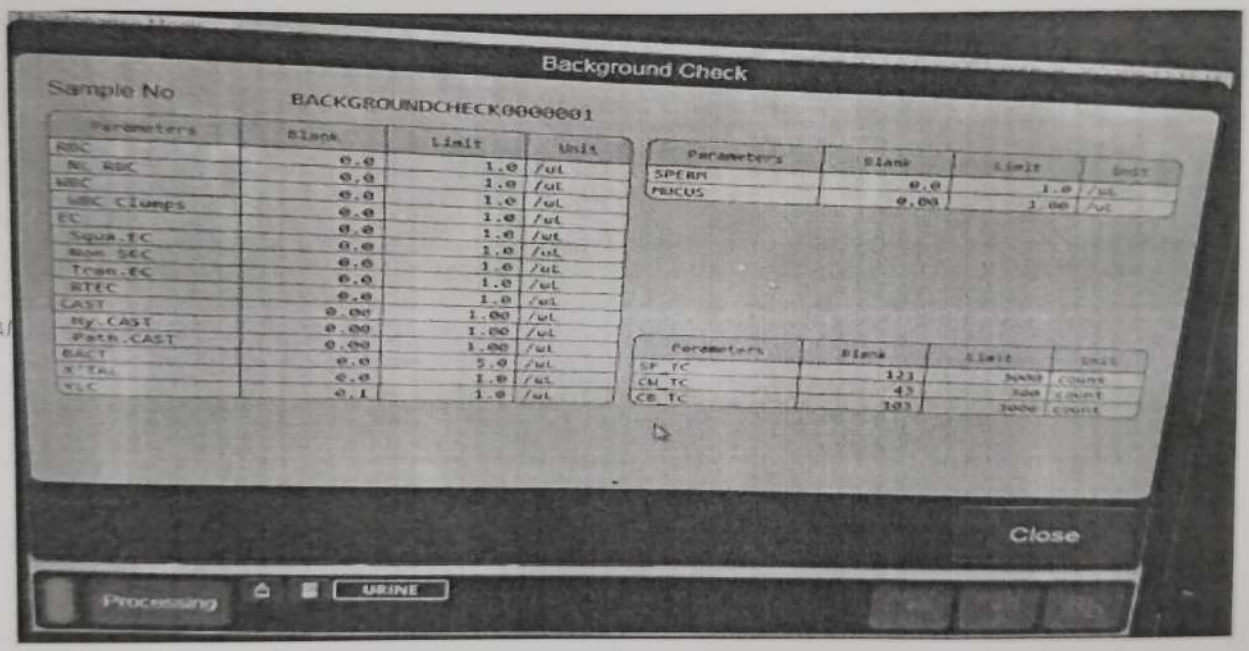
Date Time	BACT	Cond
2020/09/12 20 18 00	218.5	6.4
2020/09/12 20 21 15	223.5	7.6
2020/09/12 20 23 28	230.5	7.9

MEAN	224.1	7.3
SD	6.02	0.79
CV(%)	2.6	10.8
UL	266.1	11.8
TARGET	204.7	8.4
LL	143.3	5.0
Unit	/ul	mS/cm

A3636 00-14_Build009 2020/09/12 21 44 26 1/1

Table 11 - Result for **Control QC - H**

UF CONTROL		UF Control -H Assay Value				Status
Parameter	Result	Target	Limit	Min	Max	
RBC uL	188.0	**206.2**	41.2	165.0	247.4	Pass
WBC uL	835.3	**842.2**	168.4	673.8	1010.6	Pass
EC uL	77.5	**76.6**	38.3	38.3	114.9	Pass
CAST uL	15.58	**18.79**	9.40	9.39	28.19	Pass
BACT uL	801.8	**808.9**	202.2	606.7	1011.1	Pass
COND mS/cm	35.0	**34.8**	3.5	31.3	38.3	Pass
SF_FSC_P CH	152.3			136.5	166.9	Pass
SF_FSC_W CH	44.0			41.8	46.2	Pass
SF_FLH_P CH	111.7			80.1	148.7	Pass
SF_SSL_P CH	189.1			80.1	235.8	Pass
SF_DSS_P CH	170.0			141.5	212.3	Pass
CW_FSC_P CH	104.6			93.7	114.6	Pass
CW_FLH_P CH	93.9			64.6	124.2	Pass
CW_SSH_P CH	108.4			89.2	143.8	Pass
CW_SSL_P CH	23.7			19.5	29.3	Pass
CW_DSS_P CH	27.2			22.5	31.8	Pass
CB_FSC_P CH	164.5			147.5	180.3	Pass
CB_FLL_P CH	174.7			126.2	223.5	Pass
CB_SSH_P CH	205.5			178.2	241.1	Pass

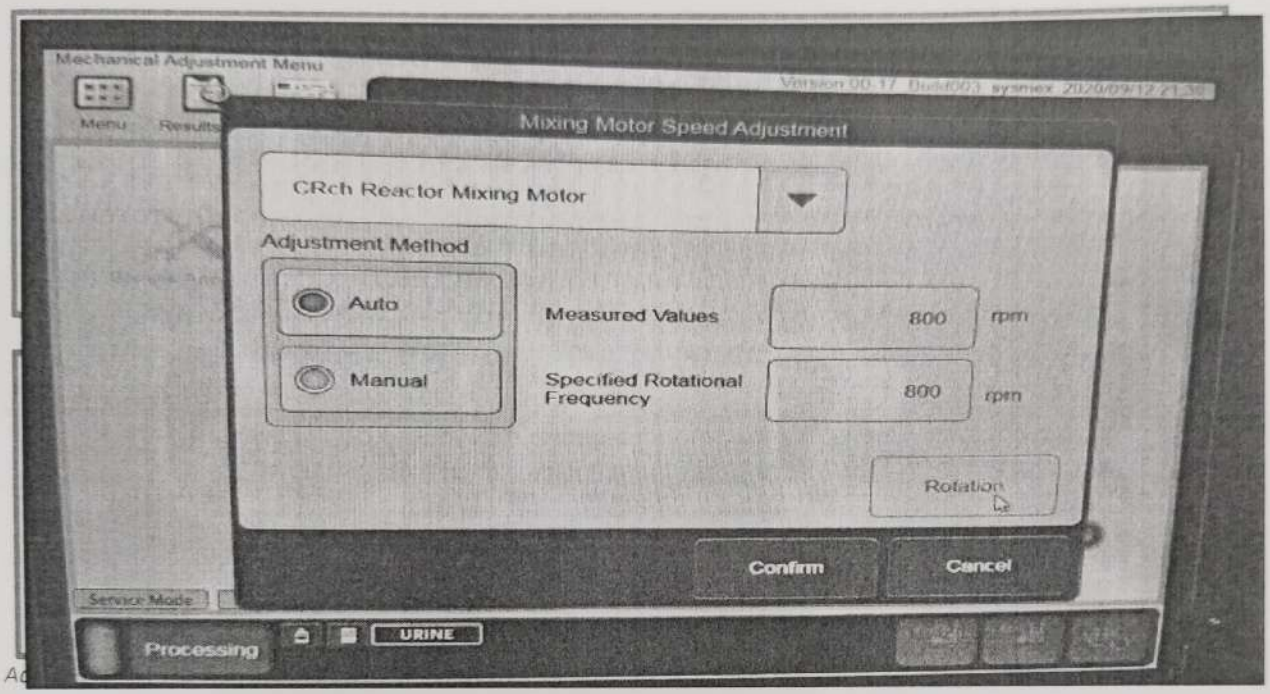

Background Check
Sample No
BACKGROUNDCHECK0000001
Parameters
Blank
Limit
Unit
RBC
0.0
1.0
/ul
NL RBC
0.0
1.0
/ul
WBC
0.0
1.0
/ul
WBC Clumps
0.0
1.0
/ul
EC
0.0
1.0
/ul
Squa.EC
0.0
1.0
/ul
Non SEC
0.0
1.0
/ul
Tran.EC
0.0
1.0
/ul
RTEC
0.0
1.0
/ul
CAST
0.00
1.00
/ul
Hy.CAST
0.00
1.00
/ul
Path.CAST
0.00
1.00
/ul
BACT
0.0
5.0
/ul
X'TAL
0.0
1.0
/ul
YLC
0.1
1.0
/ul
Parameters
Blank
Limit
Unit
SPERM
0.0
1.0
/ul
MUCUS
0.00
1.00
/ul
Parameters
Blank
Limit
Unit
SP_TC
121
5000
count
CM_TC
43
5000
count
CB_TC
103
5000
count
Close
Processing
URINE

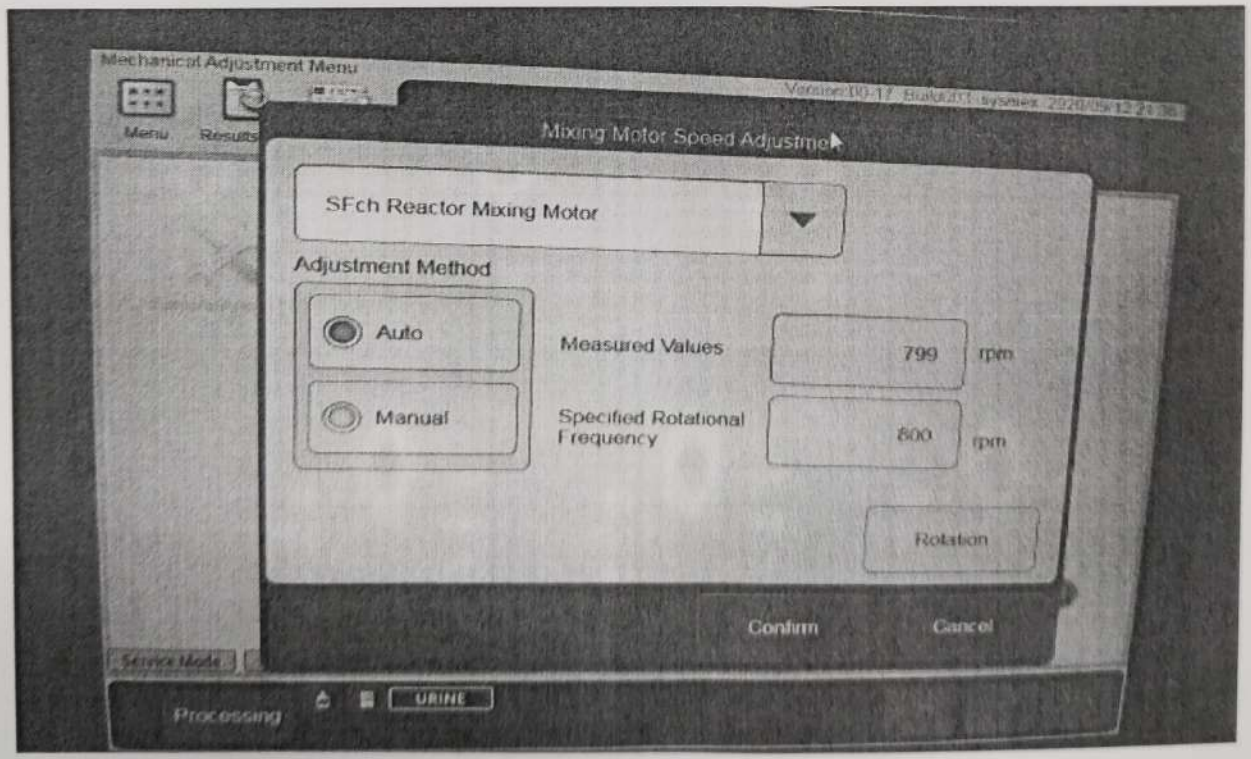
2 MIXING MOTOR VERIFICATION

2.1 Mixing Motor speed needs to be confirmed before executing the adjustment. Execute [Mixing Motor] adjustment and result is shown here:

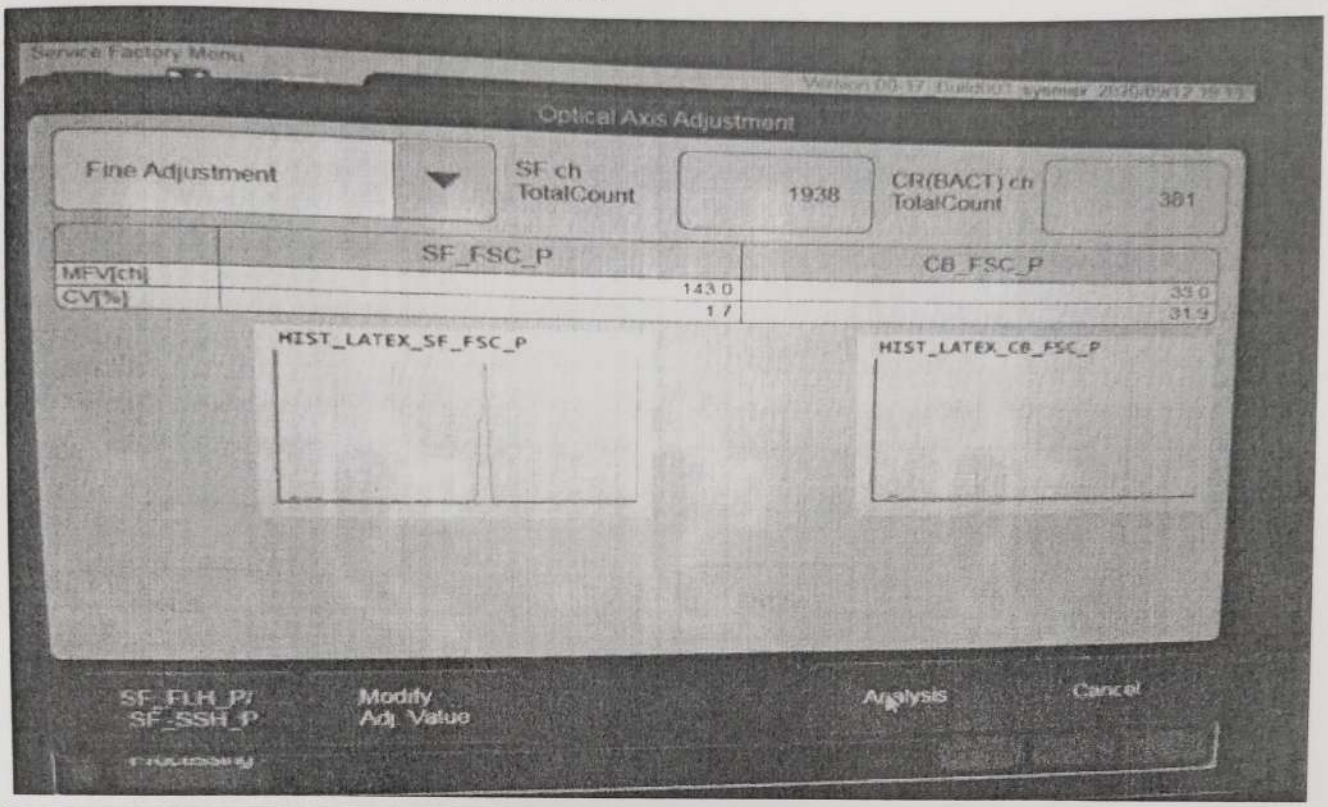
Table 2 - Mixing motor speed adjustment result

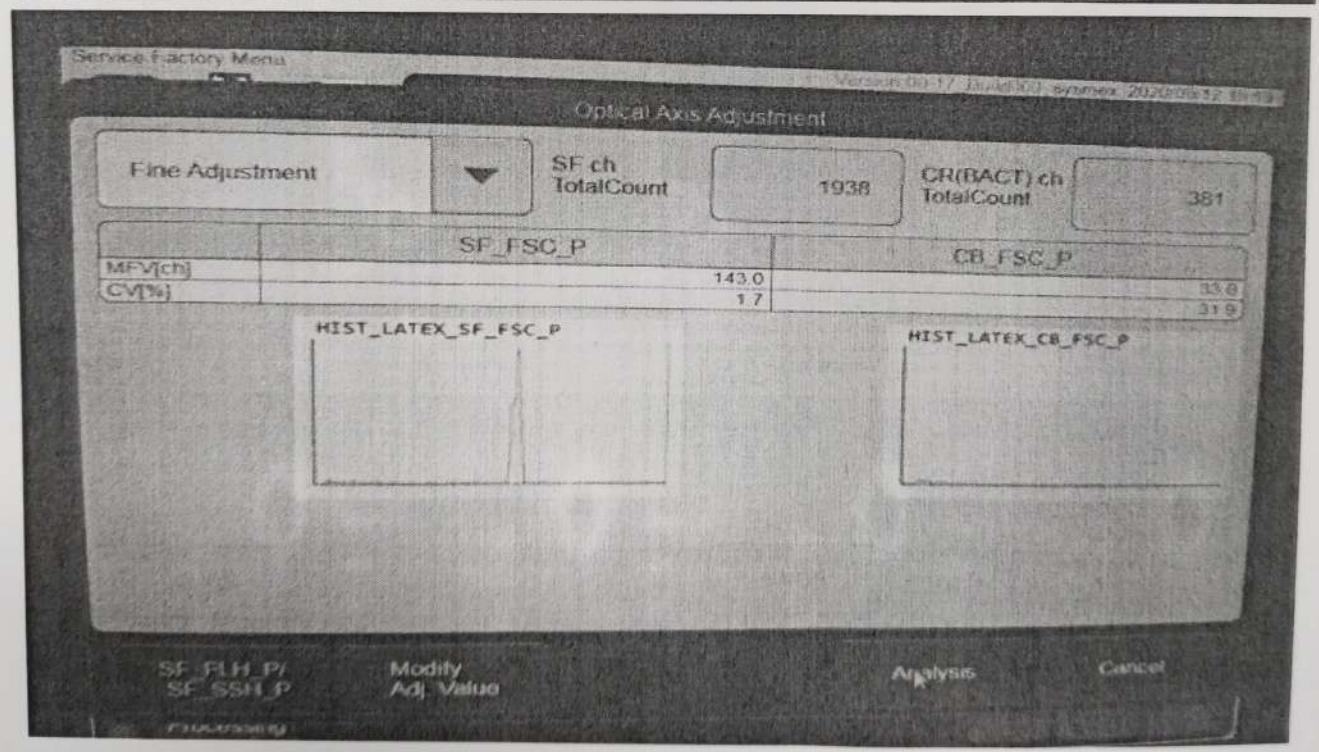
Mixing motor type	Reading	Acceptable range	Status
SFch Reactor Mixing Motor	799	750-850	Pass
CRch Reactor Mixing Motor	800	750-850	Pass

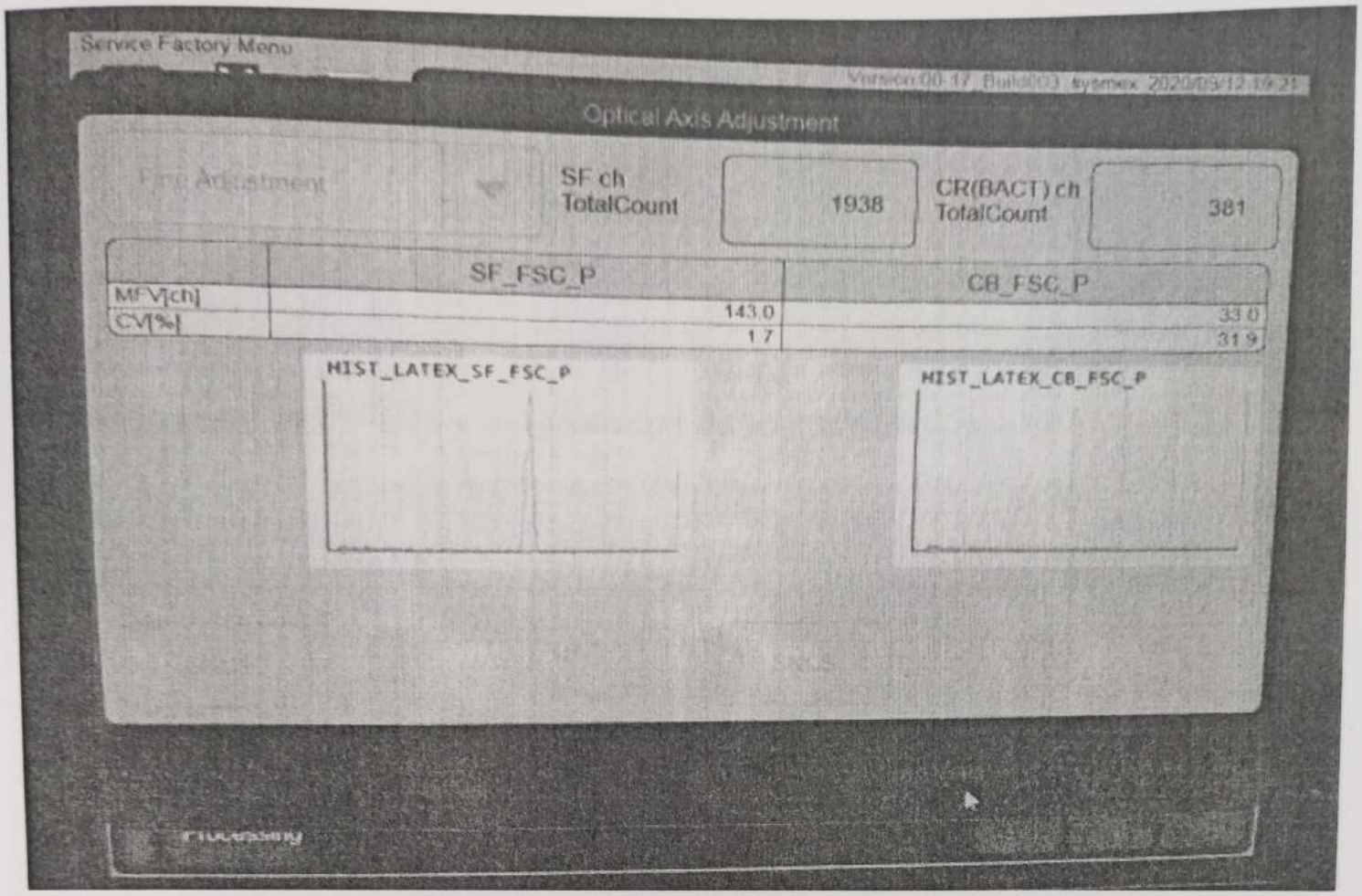




- All laser adjustments result must be attached here:



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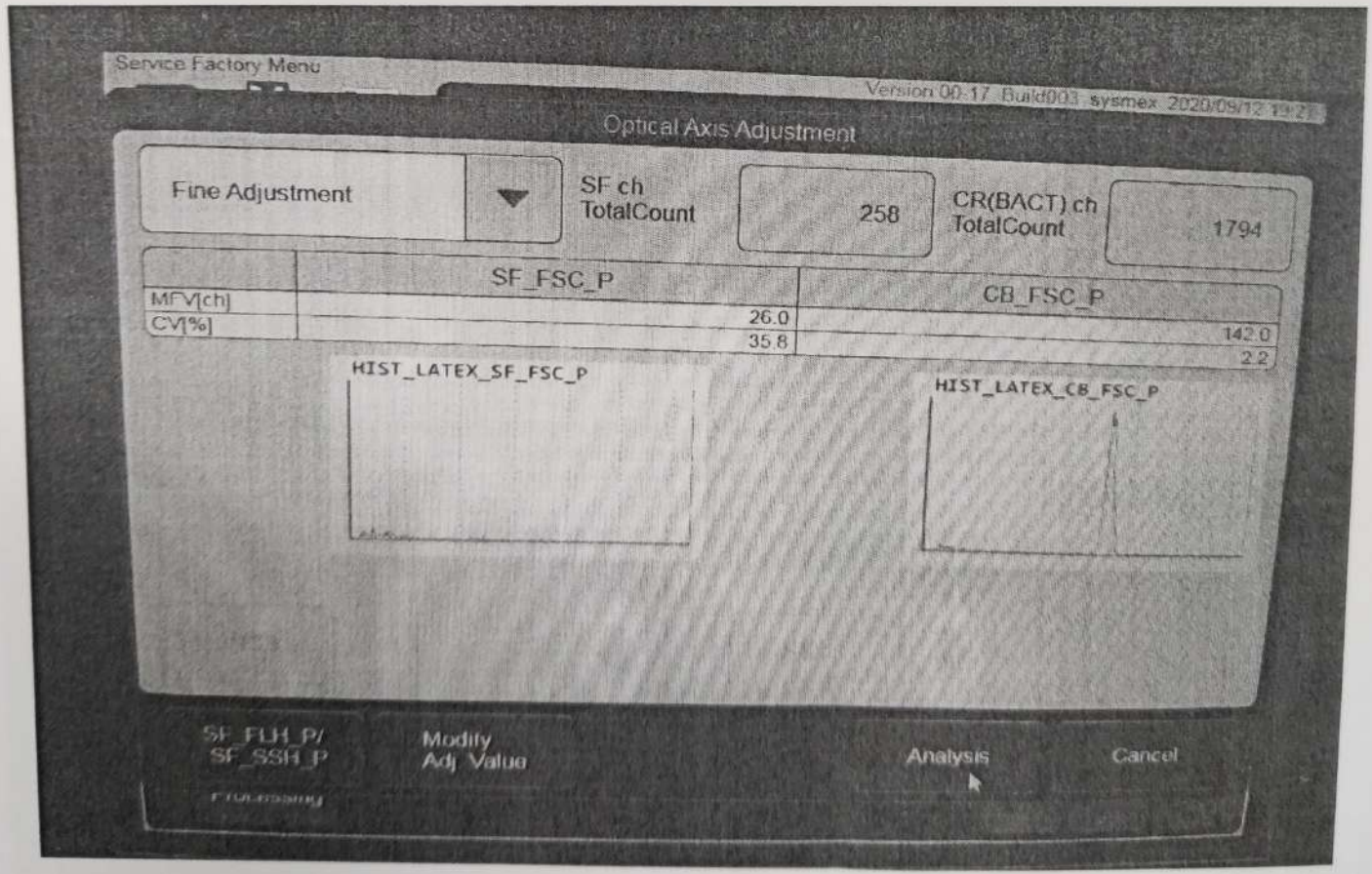
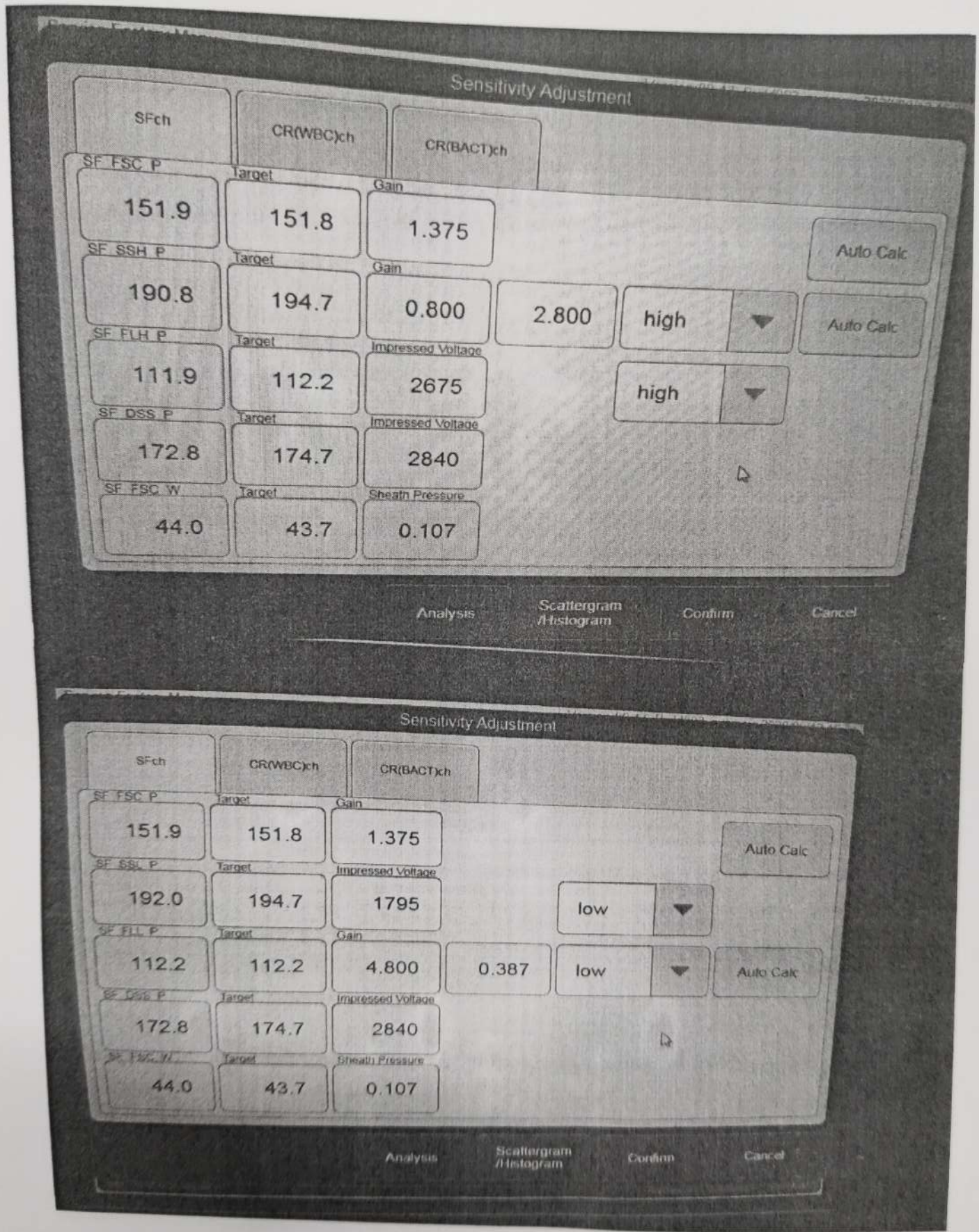
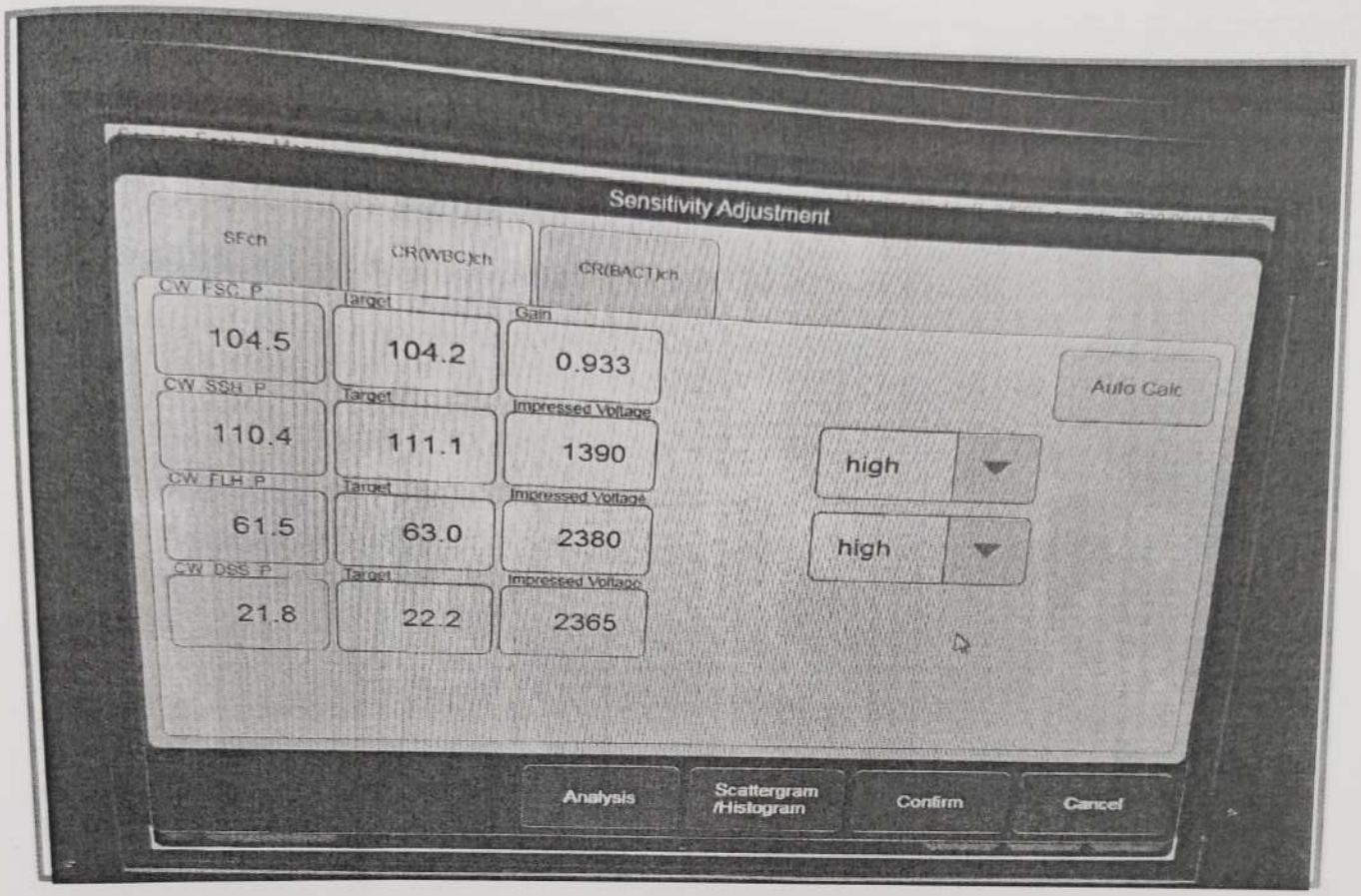
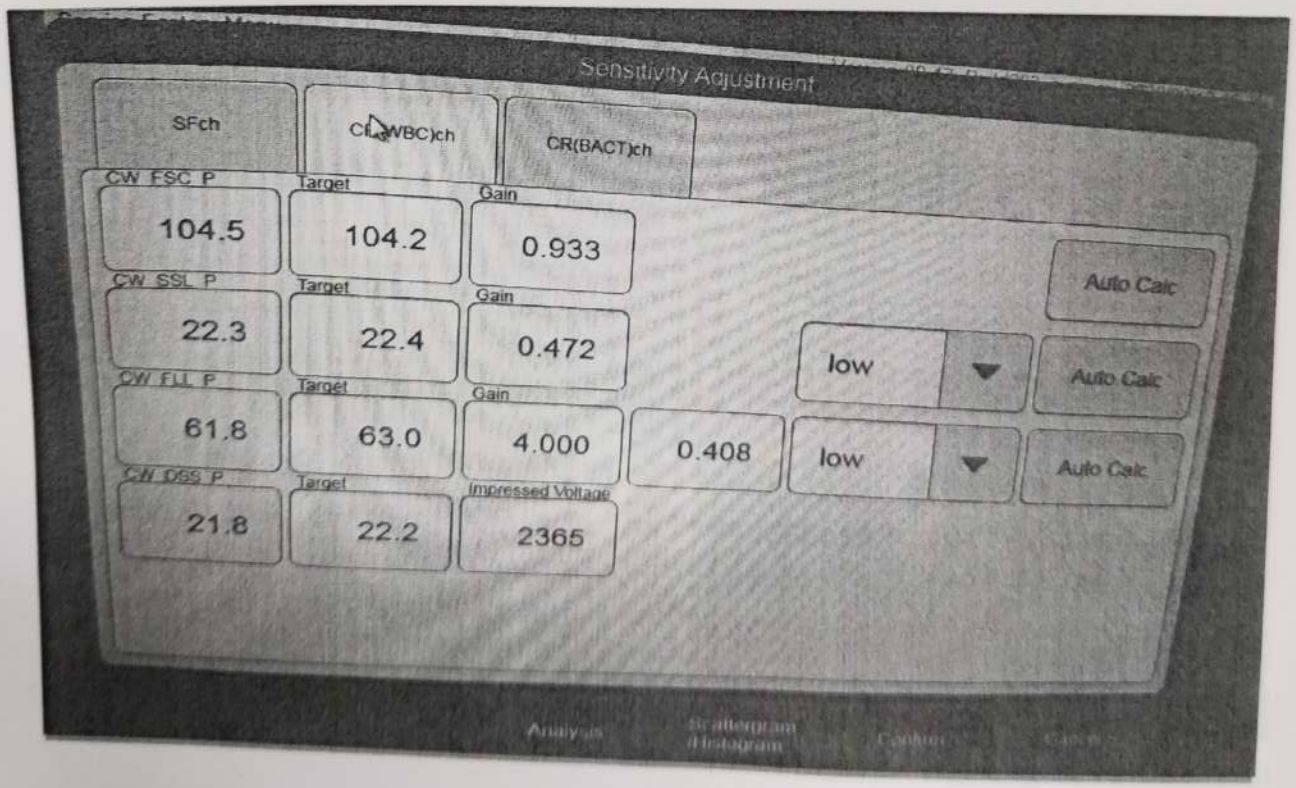
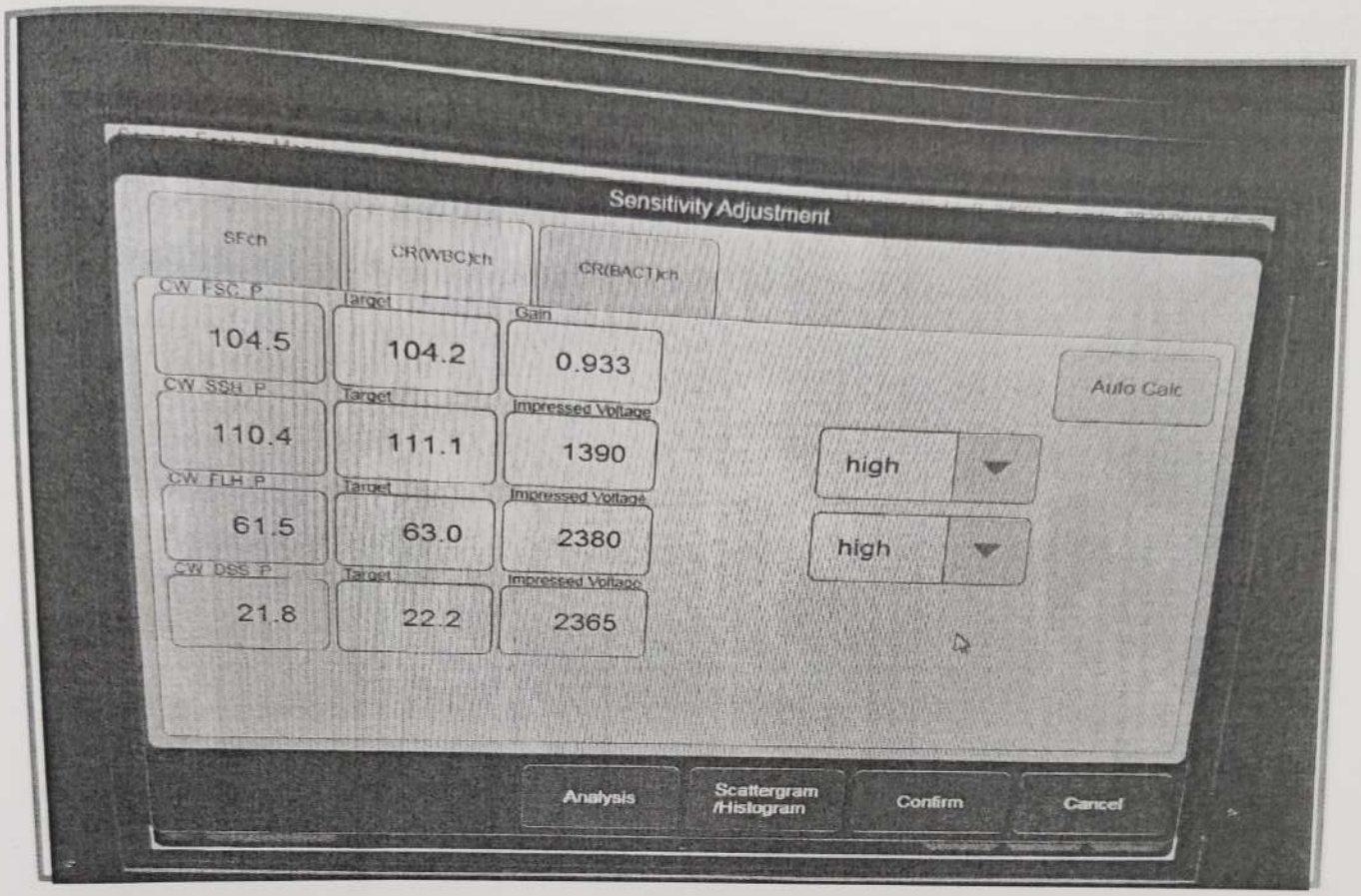
Optical Axis Adjustment
SF ch TotalCount
1938
CR(BACT) ch TotalCount
381
SF_FSC_P
CB_FSC_P
MFV[ch]
CV[%]
143.0
1.7
33.0
31.9
HIST_LATEX_SF_FSC_P
HIST_LATEX_CB_FSC_P


Service Factory Menu
Version 00-17 Build003 sysmex 2020/09/12 19:21
Optical Axis Adjustment
Fine Adjustment
SF ch TotalCount
258
CR(BACT) ch TotalCount
1794
SF_FSC_P
CB_FSC_P
MFV[ch]
CV[%]
26.0
35.8
142.0
2.2
HIST_LATEX_SF_FSC_P
HIST_LATEX_CB_FSC_P
SF_FLH_P/ SF_SSH_P
Modify Adj Value
Analysis
Cancel


Sensitivity Adjustment
SFch
CR(WBC)ch
CR(BACT)ch
SF FSC P
Target
Gain
151.9
151.8
1.375
Auto Calc
SF SSH P
Target
Gain
190.8
194.7
0.800
2.800
high
Auto Calc
SF FLH P
Target
Impressed Voltage
111.9
112.2
2675
high
SF DSS P
Target
Impressed Voltage
172.8
174.7
2840
SF FSC W
Target
Sheath Pressure
44.0
43.7
0.107
Analysis
Scattergram /Histogram
Confirm
Cancel
Sensitivity Adjustment
SFch
CR(WBC)ch
CR(BACT)ch
SF FSC P
Target
Gain
151.9
151.8
1.375
Auto Calc
SF SSL P
Target
Impressed Voltage
192.0
194.7
1795
low
SF FLL P
Target
Gain
112.2
112.2
4.800
0.387
low
Auto Calc
SF DSS P
Target
Impressed Voltage
172.8
174.7
2840
SF FSC W
Target
Sheath Pressure
44.0
43.7
0.107
Analysis
Scattergram /Histogram
Confirm
Cancel


Sensitivity Adjustment
SFch
CR(WBC)ch
CR(BACT)ch
CW FSC P
Target
Gain
104.5
104.2
0.933
Auto Calc
CW SSH P
Target
Impressed Voltage
110.4
111.1
1390
high
CW FLH P
Target
Impressed Voltage
61.5
63.0
2380
high
CW DSS P
Target
Impressed Voltage
21.8
22.2
2365
Analysis
Scattergram /Histogram
Confirm
Cancel


Sensitivity Adjustment
SFch
CR(WBC)ch
CR(BACT)ch
CW FSC P
Target
Gain
104.5
104.2
0.933
Auto Calc
CW SSL P
Target
Gain
22.3
22.4
0.472
low
Auto Calc
CW FLL P
Target
Gain
61.8
63.0
4.000
0.408
low
Auto Calc
CW DSS P
Target
Impressed Voltage
21.8
22.2
2365


Sensitivity Adjustment
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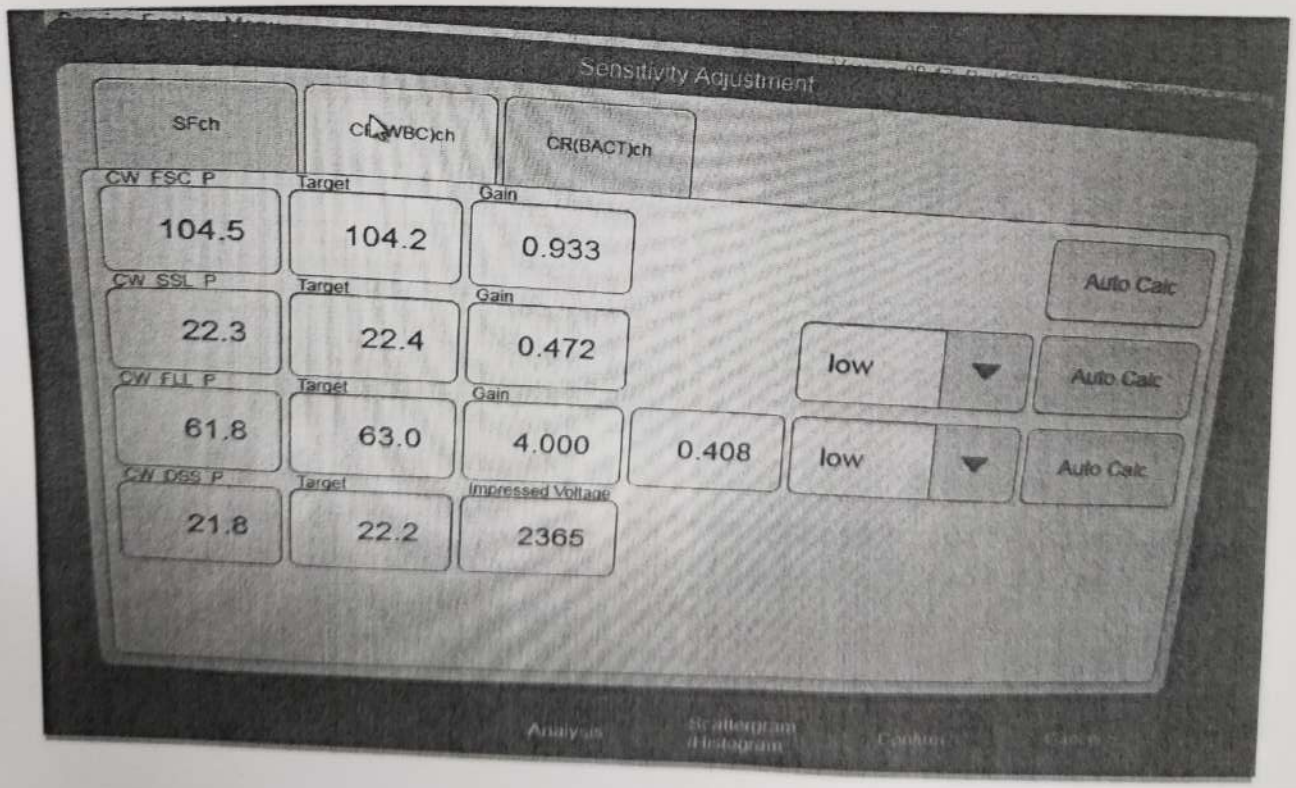
CR(WBC)ch
CR(BACT)ch
CW FSC P
Target
Gain
104.5
104.2
0.933
Auto Calc
CW SSH P
Target
Impressed Voltage
110.4
111.1
1390
high
CW FLH P
Target
Impressed Voltage
61.5
63.0
2380
high
CW DSS P
Target
Impressed Voltage
21.8
22.2
2365
Analysis
Scattergram /Histogram
Confirm
Cancel


Sensitivity Adjustment
SFch
CR(WBC)ch
CR(BACT)ch
CW FSC P
Target
Gain
104.5
104.2
0.933
Auto Calc
CW SSL P
Target
Gain
22.3
22.4
0.472
low
Auto Calc
CW FLL P
Target
Gain
61.8
63.0
4.000
0.408
low
Auto Calc
CW DSS P
Target
Impressed Voltage
21.8
22.2
2365

9 CERTIFICATION

9.1 We certify that the UF Automated Urine Particle Analyzer S/N : **11929** has been successfully calibrated in accordance with the manufacturer's recommendations.

Report and Calibration Performed By :

Signature (Engineer 1)

Name: Jakir Hussain Mondal

Date: 12 September, 2020

Report Reviewed and Accepted By :

Signature (Customer)

Name: Dr. Nito Yepthomi

Date: 14/9/2020

Dr. Nito Yepthomi
MD Pathology
Reg.No. NMC/R - 18/01006
Christian Institute of Health Sciences & Research
Dimapur, Nagaland

Signature (Engineer 1)

Name:

Date:

Company Stamp : (Vendor)

Company Stamp : (Customer)