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Development and Standardization of Calibration Methods for Equipment Used in Visual Health (Keratometers, Lensometers and Tonometers), Implemented in the Hospital Universitario de San Vicente Fundación

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Abstract **—**In the field of visual health, a series of equipment is used to aid in the diagnosis and treatment of patient pathology. However, no standardized calibration method to ensure the measurements performed with these devices exists today. The objective of the paper was to standardize calibration methods for some of the equipment used in the field of visual health such as keratometers, lensometers and tonometers. For the calibration of the three types of equipment included in this development, methods of direct comparison were used of the indication with the magnitude of the standards that had traceability with national and international laboratories accredited under the Standard NTC-ISO / IEC 17025: 2005. The measurements made by each of the technicians to the different types of equipment under repeatable conditions and using the adopted method were analyzed statistically with the simple Anova tool of STATGRAPHICS, yielding satisfactory results with a P-value above 0.05. Tests of accuracy, linearity and robustness were also performed with positive results. The adopted methods were successfully validated and later standardized under the accreditation in the NTC-ISO / IEC 17025: 2005 Standard.

Keywords **—** Calibration, validation, diopters, astigmatism, intraocular pressure, linearity, accuracy, robustness.

Desarrollo y estandarización de métodos de calibración para equipos utilizados en salud visual (Queratómetros, Lensómetros y Tonómetros), implementados en el Hospital Universitario de San Vicente Fundación

Resumen**—**En el campo de la salud visual se utilizan una serie de equipos que ayudan al diagnóstico de la patología del paciente, pero actualmente no existe un método de calibración estandarizado para asegurar las mediciones que se realizan con estos dispositivos. El objetivo era estandarizar métodos de calibración para algunos de los equipos utilizados en el campo de la salud visual como son: queratómetros, lensómetros y tonómetros. Para la calibración de los tres tipos de equipos incluidos en este

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desarrollo, se utilizaron métodos de comparación directa de la indicación con la magnitud de los patrones utilizados que tenían trazabilidad con laboratorios nacionales e internacionales acreditados bajo la Norma NTC-ISO/IEC 17025:2005. Las mediciones realizadas por cada uno de los técnicos a los diferentes tipos de equipos en condiciones de repetibilidad y utilizando el método adoptado, se hicieron estadísticamente con la herramienta Anova Simple de Statgraphics, arrojando resultados satisfactorios con un valor-P por encima de 0,05, igualmente se realizaron pruebas de exactitud, linealidad y robustez con resultados positivos. Los métodos adoptados fueron exitosamente validados y posteriormente estandarizados bajo la acreditación en la Norma NTC-ISO/ IEC 17025:2005.

Palabras clave — Calibración, validación, dioptrías, astigmatismo, presión intraocular, linealidad, exactitud, robustez.

Desenvolvimento e estandardização de métodos de calibração para equipamentos utilizados em saúde visual implementados no Hospital Universitário de San Vicente Fundación

Resumo—No campo da saúde visual utilizam-se uma série de equipas que ajudam ao diagnóstico da patologia do paciente, mas, atualmente não existe um método de calibração padronizado para assegurar as medidas que se realizam com estes dispositivos. O objetivo foi estandardizar métodos de calibração para alguns das equipas utilizadas no campo da saúde visual como são: ceratômetro, lenteômetros e tonometros. Para a calibração dos três tipos de equipamentos incluídos neste desenvolvimento, utilizaram-se métodos de comparação direta da indicação com a magnitude dos padrões utilizados que tinham rastreabilidade com laboratórios nacionais e internacionais acreditados baixo a Norma NTC-ISO/IEC 17025:2005. As medidas realizadas por cada um dos técnicos aos diferentes tipos de equipamentos em condições de repetir-se e utilizando o método adoptado, se analisaram estatisticamente com a ferramenta anova simples de statgraphics, produzindo resultados satisfatórios com um valor-P acima de 0,05, igualmente se realizaram provas de exatidão linearidade e robustez com resultados positivos. Os métodos adoptados foram validados de maneira exitosa e posteriormente padronizados baixo a acreditação na Norma NTC-ISO/ IEC 17025:2005.

Palavras-chave—Calibração, validação, dioptrias, astigmatismo, pressão intraocular, linearidade, exatidão, robustez.

I. Introduction

In the field of eye care, specifically in the areas of optometry and ophthalmology, a series of equipment is used, such as keratometers and tonometers, for diagnosis and lensometers for lens prescriptions. This equipment becomes essential for the specialist to be able to give the patient a correct diagnosis and a precise and accurate prescription.

According to the clinical application of this equipment and the importance it has at the moment of issuing a result, the need for calibration surges. This calibration results in an error report for those points evaluated, which aids the the specialist in achieving more precise and accurate diagnoses. However, there is no current standardized method of calibration for this equipment.

In view of the above, three calibration methods were developed for each one of the equipment pieces in the evaluation (keratometer, tonometer and lensometer), using direct comparison techniques with traceable patterns in all three. In this context, the end goal proposed in this paper was the validation of these developed methods, and later their standardization, through accreditation under the NTC-ISO/IEC 17025:2005 Standard.

II. Methodology

After a study of the specific techniques, operating methods and use, physical principles of phenomena associated to the equipment or its calibration magnitude, a methodology was defined for the development of a calibration procedure that would be technically apt and that could be modified or adjusted to needs.

This calibration method standardization was developed using direct comparison methods of the instructions each piece of equipment reported in the evaluation, with respect to the magnitude of patterns used, which had traceability in accredited laboratories within the NTC-ISO/IEC 17025:2005 Standard.

For keratometers, a set of spheres were used, with diameters corresponding to the interval of diopters found in the average of registered readings normally found for this equipment, equivalent to the curvature of the human eye (40,50 D; 42,25 D; 45,00 D). In the case of tonometers, a set of four non-regulated weights, each one equal to an intraocular pressure value of 20 mmHg, which represents the force used to flatten the cornea. For lensometers, a set of spherical lenses and one cylindrical lens, which covers the normal work interval of the equipment (-20 D a +20 D), were used. The sample for each class of devices were three different types of equipment which included the analogical or digital indications that were normally found in commercial brands.

For the validation of the method, four (4) metrologists performed five (5) calibrations for each one of the three (3) equipment pieces selected. These measurements were carried out under repetitive conditions, controlling the magnitude of influence that might affect the test, as in the case of ambient temperature, established at 20 ºC ± 2 ºC.

For method robustness tests, tests were performed in locations with different altitudes above sea level, where, in addition to altitude, temperature also changes.

The uncertainty associated to each method, force and mass (6, 7, 8) for tonometer and dimensional magnitude (9) for keratometers and lensometers, were studied and selected in accordance with reference standards.

In the analysis of results, the Anova test was used to find the difference of the average of each point evaluated between one metrological level and another. Statistical differences of p <0,05 for the F-ratio were considered for a level of accuracy of 95%.

In order to determine the linearity of the calibration methods the t-student test was used. Statistical differences for a p <0,05 were considered.

III. Results

Results for each metrologist through the direct comparison method with work patterns for each one of the equipment pieces evaluated were analyzed using simple Anova as a statistical method to determine the repetitiveness and reproducibility, through the STATGRAPHICS tool. The ANOVA chart decomposes the variance of each one of the evaluated points in two components: one inter-group component and one intra-group component. The F-ratio, is the coefficient between the estimated inter-group and the estimated intra-group, since the P-value of the F-ratio is greater or equal to 0.05. There is no significant statistical difference of the average of each point evaluated between one metrologist and another, with an accuracy level of 95.0%. Results are found in Tables 1, 2 and 3.

Table 1. Anova Table. Measurement results for all three tonometers

Equipment	Evaluated point (mmHg)	F-ratio	P-Value
Tonometer Brand: Luxury Series: 4254	20	1.18	0.3500
	40	0.02	0.9999
	60	0.02	0.9998
	80	0.04	0.9992
Tonometer Brand: Zeiss Model: AT030	20	0.16	0.9246
	40	1.52	0.2481
	60	0.03	0.9923
	80	0.24	0.8655
Tonometer Brand: Luxury Model: YX-30R	20	0.55	0.6582
	40	0.04	0.9884
	60	0.56	0.6469
	80	0.47	0.7052

Table 2. Anova Table. Measurement results for all three keratometers

Equipment	Evaluated point (D)	F-ratio	P-Value
Digital Keratometer Brand: Nidek Model: ARK 500A Series: 530308	40.50	0.57	0.7209
	42.25	0.08	0.9947
	45.00	0.06	0.9968
Digital Keratometer Brand: Nidek Model: APK 500A Series: 530265	40.50	0.01	0.9993
	42.25	0.17	0.9165
	45.00	0.01	0.9992
Analog Keratometer Brand: Topcon Model: OM-4 Series: 3026339	40.50	0.48	0.7000
	42.25	0.06	0.9784
	45.00	0.02	0.9952

D = Diopters

Table 3. Anova Table. Measurement results for all three lensometers

Equipment	Evaluated point (D)	F-ratio	P-Value
Digital Lensometer Brand: Topcon Model: CL 200 Series: 3903285	+5	0.54	0.7425
	-5	0.03	0.9996
	+10	0.11	0.9882
	-10	0.04	0.9989
	-13	1.09	0.3905
	+20	0.10	0.9912
	-20	0.33	0.8909
	10 (Cylinder)	0.09	0.9922
Digital Lensometer Brand: Nidek Model: LM-500 Series: 404750	+5	0.37	0.7770
	-5	0.05	0.9837
	+10	0.32	0.8113
	-10	0.51	0.6807
	-13	0.04	0.9876
	+20	0.10	0.9589
	-20	0.35	0.7923
	10 (Cylinder)	0.02	0.9970
Analog Lensometer Brand: Nidek Model: LM-770 Series: 0503610	+5	0.24	0.8661
	-5	0.03	0.9931
	+10	0.05	0.9831
	-10	0.07	0.9739
	-13	0.12	0.9483
	+20	0.31	0.8211
	-20	0.14	0.9375
	10 (Cylinder)	0.03	0.9918

D = Diopters

Furthermore, the linearity, accuracy and robustness of the method was evaluated in order to determine validity. Linearity enabled the establishment of the capacity of the method within a determined interval, as well as, giving instrument responses or results proportional to the evaluated point. In quality, the method is linear, evaluating the correlation coefficient R2, which is greater than 0.99. This means that there is a high probability correlation. However, in order to obtain a better linear indication, we used a t-student statistical tool, obtaining compliance results of (10). The results of these tests are found in Tables 4, 5 and 6 and Figs.1, 2 and 3.

Table 4. Average results of the average of each point measured in the three different tonometers to determine linearity of the calibration method through a t-student test

EVALUATED POINTS (mmHg)	Tonometer Brand: Luxury Series: 4254	Tonometer Brand: Zeiss Model: AT030	Tonometer Brand: Luxury Model: YX-30R
20	20.03400	19.965	19.517
40	40.08833	40.009	39.500
60	60.53200	60.033	59.452
80	81.11400	79.942	78.977
Slope	1.01842	0.99978	0.99166
Intercept	-0.47884	-0.00150	-0.22150
Correlation Coefficient "r"	0.99998	1.00000	0.99998
Correlation Coefficient " R² "	0.99996	1.00000	0.99997
t Cal	238.788	893.556	255.446
t Critical	6.205	6.205	6.205
Criteria Linear compliment	t CAL ≥ t CRITICAL		

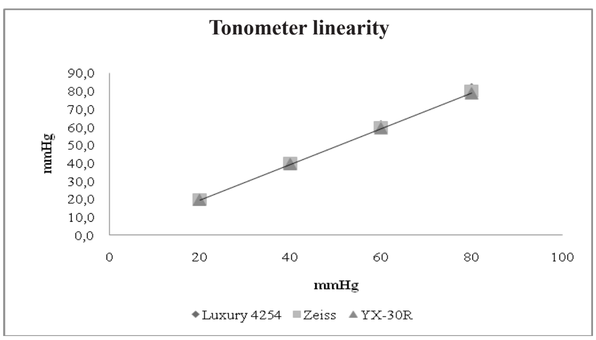

Fig. 1. Linearity of calibration method for tonometers

Table 5. Average results of averages of each point measured in the three different keratometers used to determine linearity of the calibration method through a t-student test

EVALUATED POINTS (DIOPTRIAS)	Digital keratometer Brand: Nidek Model: ARK 500A Series: 530308	Digital keratometer Brand: Nidek Model: ARK 500A Series: 530265	Analog keratometer Brand: Topcon Model: OM-4 Series: 3026339
40.50	40.5026	40.63565	40.505
42.25	42.15917	42.35625	42.2375
45.00	45.00197	45.1491	45.01575
Slope	1.00288	1.00411	1.00309
Intercept	-0.15129	-0.04471	-0.12888
Correlation Coefficient " r "	0.99972	0.99996	0.99999
Correlation Coefficient " R² "	0.99945	0.99992	0.99997
t Cal	42.63107	114.85658	183.27524
t Critical	25.4517	25.4517	25.4517
Criteria Linear compliment	**t cal ≤ t critical**		

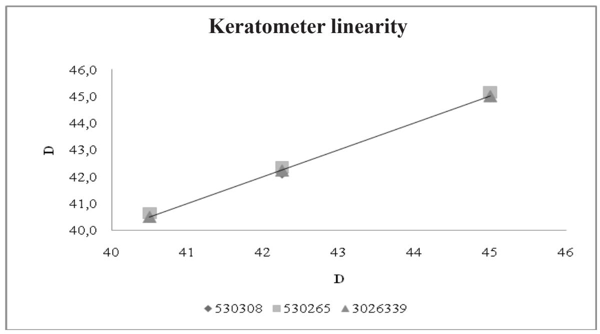

Fig. 2. Linearity of calibration methods for keratometer

Table 6. Average results of averages of each point measured in the three different lensometers used to determine linearity of the calibration method through a t-student test

EVALUATED POINTS (DIOPTERS)	Digital Lensometer Brand: Topcon Model: CL 200 Series: 3903285	Digital Lensometer Brand: Nidek Model: LM-500 Series: 404750	Analog Lensometer Brand: Nidek Model: LM-770 Series: 0503610
5	5.0545	5.09351	5.02425
-5	-4.99653	-5.0494	-5.1115
10	10.38697	10.43582	10.40175
-10	-10.03333	-10.14363	-10.177
-13.3	-13.28597	-13.42956	-13.42525

20	21.05327	21.0996	21.02975
-20	-19.88747	-20.1256	-20.1595
10	10.3226	10.40485	10.4125
Slope	1.02045	1.02824	1.02759
Intercept	0.24769	0.20985	0.17326
Correlation Coefficient "r"	0.99987	0.99991	0.99991
Correlation Coefficient " R^2 "	0.99973	0.99982	0.99982
t Cal	149.99988	181.36291	180.23781
t Critical	2.96869	2.96869	2.96869
Linear compliment criteria	t CAL ≥ t CRITICAL		

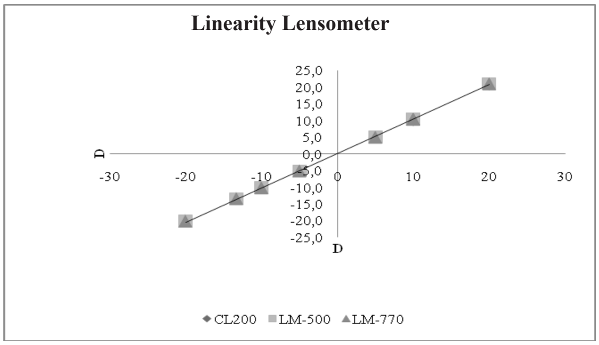

Fig. 3. Linearity of calibration method for Lensometer

The accuracy is applied to a set of results of a calibration and assumes a combination of random components and a common component of systematic error or skew. When applied to a calibration method, the term "accuracy" refers to a combination of veracity and precision. In this test, the degree of existing coincidence was determined between the average value obtained from a series of results from each metrologist and a reference value. A t-student statistical test tool was used (10). Results are found in Tables 7, 8 and 9.

Table 7. Average results of the average of each point measured in the three different tonometers to determine the Accuracy of the calibration method through a t-student test

Points Evaluated (mmHg)		**20**	**40**	**60**	**80**
Tonometer Brand: Luxury Series: 4254	**Average of averages (mmHg)**	20.03	40.088	60.532	81.11
	Reference value (mmHg)	20	40	60	80
	Slant (mmHg)	0.03	0.088	0.532	1.114
	Standard deviation (mmHg)	0.119	0.08	0.21	0.323
	n	20	20	20	20
	t cal	0.05	0.2	0.46	0.63
	t critical	2.36	2.36	2.36	2.36
Tonometer Brand: Zeiss Model: AT030	**Average of averages (mmHg)**	19.965	40.018	60.033	79.94
	Reference value (mmHg)	20	40	60	80
	Slant (mmHg)	-0.04	0.018	0.033	-0.058
	Standard deviation (mmHg)	0.036	0.08	0.045	0.017
	n	20	20	20	20
	t cal	-0.22	0.05	0.17	-0.76
	t critical	2.43	2.43	2.43	2.43
Tonometer Brand: Luxury Model: YX-30R	**Average of averages (mmHg)**	19.517	39.5	59.452	78.98
	Reference value (mmHg)	20	40	60	80
	Slant (mmHg)	-0.48	-0.5	-0.548	-1.023
	Standard deviation (mmHg)	0.018	0.033	0.036	0.039
	n	20	20	20	20
	t cal	-6.17	-3.38	-3.37	-5.94
	t critical	2.43	2.43	2.43	2.43
Compliance criteria		**t cal ≤ t critical**			

Table 8. Average results of the average of each point measured in the three different keratometers to determine the Accuracy of the calibration method through a t-student test

Points Evaluated (D)		**40,50**	**42,25**	**45,00**
Digital Keratometer Brand: Luxury Series: 530308	**Average of averages (D)**	40.5026	42.159	45.002
	Reference value (D)	40.4936	42.186	45.02
	Slant (D)	0.009	-0.027	-0.0193
	Standard deviation (D)	0.002	0.103	0.002
	n	20	20	20
	t cal	0.99	0.05	2.23
	t critical	2.36	2.36	2.36
Digital Keratometer Brand: Nidek Model: ARK 500A Series: 530265	**Average of averages (D)**	40.63565	42.356	45.1491
	Reference value (D)	40.4936	42.186	45.02
	Slant (D)	0.142	0.1701	0.1278
	Standard deviation (D)	0.074	0.017	0.065
	n	20	20	20
	t cal	0.43	2.2	0.44
	t critical	2.43	2.43	2.43
Analog Keratometer Brand: Topcon Model: OM-4 Series: 3026339	**Average of averages (D)**	40.505	42.238	45.0158
	Reference value (D)	40.4936	42.186	45.02
	Slant (D)	0.0114	0.0513	-0.0055
	Standard deviation (D)	0.01	0.013	0.008
	n	20	20	20
	t cal	0.27	0.9	0.15
	t critical	2.43	2.43	2.43
Compliance criteria		**t cal ≤ t critical**		

D = Diopters

Table 9. Average results of the average of each point measured in the three different lensometers to determine the Accuracy of the calibration method through a t-student test

Points Evaluated (D)		5,00	-5	-10	20	10 CYL
Digital Lensometer Brand: Topcon Model: CL200 Series: 3903285	**Average of averages (D)**	5.05	-5.00	-10.03	21.05	10.32
	Reference value (D)	5.07	-5.05	-10.16	21.07	10.41
	Slant (D)	-0.02	0.00	0.07	-0.02	-0.08
	Standard deviation (D)	0.00	0.00	0.01	0.01	0.01
	n	20.00	20.00	20.00	20.00	20.00
	t cal	2.10	0.32	2.14	0.42	2.35
	t critical	2.36	2.36	2.36	2.36	2.36
Digital Lensometer Brand: Nidek Model: LM-500 Series: 404750	**Average of averages (D)**	5.09	-5.05	-10.14	21.10	10.40
	Reference value (D)	5.07	-5.05	-10.16	21.07	10.41
	Slant (D)	0.02	0.00	0.02	0.03	0.00
	Standard deviation (D)	0.01	0.00	0.01	0.00	0.01
	n	20.00	20.00	20.00	20.00	20.00
	t cal	0.84	0.30	0.66	1.72	0.09
	t critical	2.43	2.43	2.43	2.43	2.43
Analog Lensometer Brand: Nidek Model: LM-770 Series: 0503610	**Average of averages (D)**	5.02	-5.11	-10.18	21.03	10.41
	Reference value (D)	5.07	-5.05	-10.16	21.07	10.41
	Slant (D)	-0.05	-0.07	-0.02	-0.04	0.01
	Standard deviation (D)	0.01	0.02	0.02	0.02	0.02
	n	20.00	20.00	20.00	20.00	20.00
	t cal	1.04	0.95	0.24	0.44	0.08
	t critical	2.43	2.43	2.43	2.43	2.43
Compliment criteria		**t cal ≤ t critical**				

D = Diopters

The robustness is a measurement of the capacity of a calibration procedure to not be affected by small variations, but the deliberate one of the method parameter. It provides an indication of the reliability of the procedure under normal use. In this sense, the objective of the robustness test is to optimize the calibration method developed by the lab and to describe under which analytical conditions (including tolerance) reliable results can be obtained. Tests were performed under two different environments where ambient temperature conditions, as well as barometric pressure, were extreme, determining for each variation, if it is sensitive to the developed method (10).

The methods developed were accredited under the NTC-ISO/IEC 17025:2005 Standard, "General requirements for the Competency of Trial and Calibration Labs," by the Colombian National Accreditation Organism (*Organismo Nacional de Acreditación en Colombia - ONAC*, in Spanish). The scope of the accreditation is summarized in Table 10.

Table 10. Scope of accreditation under NTC-ISO/IEC 17025:2005 Standard

Magnitude	Measurement Intervals	CMC	Instruments to calibrate
Radius of Curvature - Dioptric Pressure	(40.50 A 45.00) D (7.54 A 8.33) mm	± 0.0069 D ± 1.1 μm	Digital keratometer, Auto refracto keratometer. On site & lab installations
	(40.50 A 45.00) D (7.54 A 8.33) mm	± 0.018 D ± 3.0 μm	Analog keratometer on site & lab installations
Dioptric Pressure	SPHERES (± 5 A ± 20) D CYLINDERS 10 D	± 0.0086 D	Digital lensometer on site & lab installations
	SPHERES (± 5 A ± 20) D CYLINDERS 10 D	± 0.022 D	Analog lensometer on site & lab installations
Eye Pressure	(20-80) mmHg (2.66 - 10.66) kPa	±0.095 mmHg ±0.013 kPa	GOLDMAN TONOMETER (w/ toll system) on site & lab installations

CMC = Calibration Measurement Capacity

IV. Discussion

Methods for the calibration of tonometers, keratometers and lensometers were developed based on direct comparison of readings with traceable results. This achievement adds to the importance of Colombia's growth in the context of metrology, which also generates recognition in more that 85 signing countries of the multilateral results, thanks to the accreditation granted under the NTC– ISO/IEC 17025:2005 Standard, received by the Colombian National Accreditation Organism (*Organismo Nacional de Acreditación en Colombia - ONAC*, in Spanish).

The uncertainty estimated for each measurement process that is reflected in the scope of accreditation on table 10 was duly budgeted, according to a precise analysis and with the support of various regulatory references, considering some components the equipment contributed during tests, other contributions by pattern equipment used for each measurement, along with the influence of the medium in which the measurements were performed as in the case of temperature. Finally, an expanded uncertainty is reported with a coverage factor of k=2 and an accuracy level of 95%.

Upon application of robustness tests, taking into consideration the exhaustive revision and inclusion of the components of uncertainty that might influence calibration results, a reliable method was obtained for the variations of the parameters that might affect measurements.

Although the participation in inter-laboratory tests is one of issues to be considered to demonstrate the validity of the calibration methods, in this case it was not possible due to the fact no offer was found from official national or international institutions for aptitude testing. This resulted in the ONAC issuing an acceptance letter in which it specifies that the test is not applicable.

V. Conclusion

After the treatment and analysis of the results of the measurements performed under conditions of repetitiveness of three different types of equipment by a team of metrologists, it is concluded that the calibration methods developed are valid, because their repeatability and reproducibility proven by the Anova method are within the established parameters by the tools, as well as, the linearity, accuracy and robustness of the method.

The results of the repeatability and reproducibility tests enabled concluding that the applied method, the pattern equipment used and the technical personnel involved comply with the necessary parameters for be considered a standard method, guaranteeing the assurance of the quality of the measurements.

The statistical analysis of the results obtained in the calibrations indicates that the method is repeatable and reproducible, that the personnel is suitable and the pattern equipment is reliable.

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