

## ELIPSE E3 HELPS PHARMA SOLUTIONS IMPLEMENT PAPERLESS RECORD SYSTEM ACCORDING TO ANVISA AND FDA CFR21 TITLE 11 STANDARDS

**Solution by Elipse Software issues reports with information corroborating the quality of weighing and unrejected products from the company's BD300 scales**

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### Needs

[Pharma Solutions Brasil](#) works with a roster of different pharmaceutical, cosmetic, and food industries that are located, for the most part, in major urban centers in Brazil. For more than 15 years, the company has provided practical, high-technology, reliable solutions, with compact systems and equipment that are easy to operate and have an excellent cost/benefit ratio.

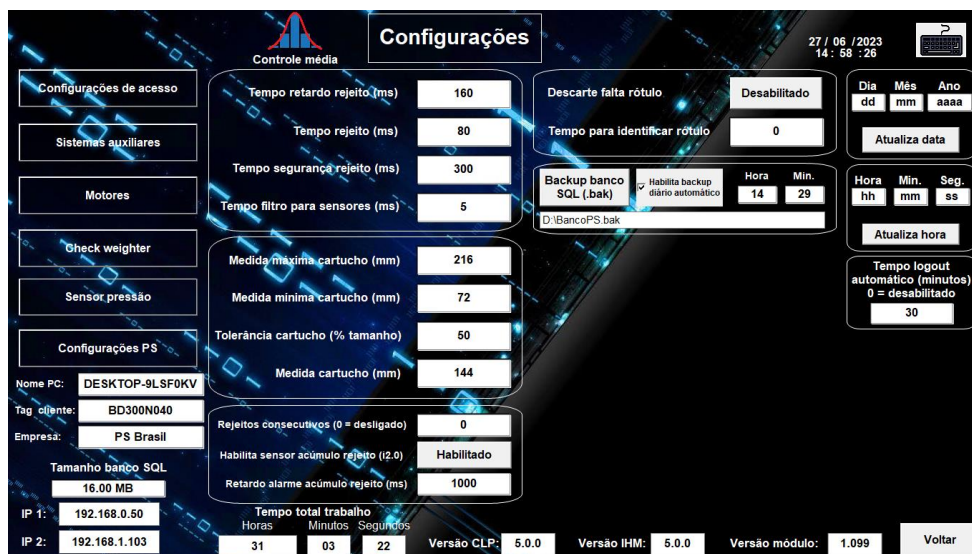
One such equipment piece is the BD300 dynamic scales, which can weigh items on queue, so that the cosmetic or drug product is sent to conveyor belts. If the item's weight differs from the established parameters, the product is discarded. The whole process takes place at the high speed of around 300 products weighed per minute.



In order to better manage the weighing process remotely, Pharma Solutions has opted for [Elipse E3](#). According to Diego Pereira, the company's Engineering and Automation Supervisor, [Elipse Software](#)'s platform was chosen due to how easily it can integrate to databases and to its ability to export reports, mainly in PDF, which comply to the standards for FDA CFR21 Title 11. Access [our article](#) to know more about how Elipse E3 applications are used in environments regulated by FDA CFR21 Title 21.

## Solution

The dynamic scale's architecture comprises three parts: an industrial PC running Elipse E3, a Siemens PLC, and a weighing module. The Elipse solution provides parametrization, that is, the best suited control for the equipment's (the whole scale's hardware) proper operation.



**Controlling the scale's configurations**

Via screens, Elipse E3 allows controlling in real time the number of units being weighed per minute and whether their weight and size obey the parameters for it. Other data being monitored include how fast each unit passes through the conveyor belt and the number of rejected products (that is, products that don't meet the standards).



**Controlling weight, speed, and number of approved/rejected units**

Throughout this process, Eclipse E3 monitors alarms, events, and historics for selected time intervals; the resulting data is displayed on screens or reports that can be exported and printed in PDF and other formats. These reports allow Pharma Solutions to demonstrate that the products not rejected by the scales do comply to the standards stipulated by Anvisa and FDA CFR21 title 11, respectively the Brazilian and the international regulatory agencies that ensure the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices.

**Histórico**    27 / 06 / 2023 14:56:11

Id	Produto	Início	Fim	Lote	Operador	Pesagens	Aprovados	Rejeitados	Média	DP	% Aprov.	% Reprov.	Maior peso	Me...
175	OPH40	26/06/2023	26/06/2023		Diego	0	0	0	26,8	0,14	12,50%	87,50%	27	26,6
176	OPH40	26/06/2023	26/06/2023		Diego	0	0	0	25,3	0,14	100,00%	0,00%	25,6	25,1
177	OPH40	26/06/2023	26/06/2023		Diego	5	4	1	26,5	0,76	33,33%	66,67%	27,6	24,3
178	OPH40	26/06/2023	26/06/2023		Diego	3	3	0	26,8	3,05	23,08%	76,92%	28,7	21,1
179	ACTIVE	26/06/2023	26/06/2023		Diego	0	0	0	24,6	0,19	100,00%	0,00%	25	24,4
180	Natu5	26/06/2023	26/06/2023		Diego	5	2	3	24,4	0,41	80,00%	20,00%	25,1	23,6
181	Natu5	26/06/2023	26/06/2023		Diego	0	0	0	26,8	0,23	11,11%	88,89%	27,4	26,6
182	OPH40	26/06/2023	26/06/2023		Diego	0	0	0	28	0,65	0,00%	100,00%	28,5	26,3
183	ACTIVE	26/06/2023	26/06/2023		Diego	21	3	18	26,1	4,16	9,58%	90,32%	29	10,6
184	ACTIVE	26/06/2023	26/06/2023		Operador	36	11	25	24,9	4,08	30,56%	69,44%	43,2	19,2

Registro: 179 de 185

**Filtros**

Data inicial: 29/3/22 0:00    Data final: 27/6/23 14:55    Mostra tudo    Consulta Data

Lote:    Consulta lote    PDF    Exportar pendrive

OP:    Consulta OP    Exportar unidade D    Exportar

OP:    Nome produto: OPH40    Lote:    Operador: Diego

Desvio padrão: 3,05g	Maior peso: 28,70g	Média: 26,80g	Observações início lote:
% aprovados: 23,08%	Menor peso: 21,10g	Pesagens: 3	
% rejeitados: 76,92%	Tempo total lote: 0d 00:01:38	Aprovados: 3	Observações fim lote:
Sp. Peso min: 22,61g	Tempo parado: 0d 00:00:00	Rejeitados: 0	
Sp. Peso: 24,61g	Quantidade paradas: 10	Data / Hora início: 26/6/23 14:21	
Sp. Peso máx: 28,61g	Data validade: 01/01/00	Data / Hora fim: 26/6/23 14:23	
		Média unid. / min.: 11,0 u/m	Exportar pendrive    Exportar unidade D    Exportar

**Weighing history per product batch**

## Benefits

- Reports can be exported and printed in PDF and other formats. These documents contain data corroborating that the weight and quality of unrejected products that passed through Pharma Solutions scales do comply with standards set by Anvisa and FDA CFR21 title 11.
- Easy integration with SQL Server database.
- Easy integration between alarms and databases for generating reports.
- Controls scales' hardware parameterization.
- Controls speed parameters in conveyor belts, filters, alarms, events, and historics.
- All data from weighing, charts, logs, reports, alarms, and others, can be stored in a reliable database.
- Simple, intuitive interface for generating reports at any time.

## Datasheet

**Client:** Pharma Solutions Brasil Ltda.

**Eclipse product:** Eclipse E3

**Platform:** Windows 10 PRO

**Number of copies:** 1 for each dynamic scale

**I/O points:** 139

**I/O drivers:** Siemens Mprot and Modbus