



The science behind the strip — hydrophilicity

Solventum MedTech OEM

Management of diabetes has come a long way thanks to medical device innovations, such as blood glucose meters and glucose test strips. Blood glucose monitoring devices have become common place and are important tools in the management of diabetes. Among the critical factors in glucose monitoring system design is the choice of quality materials and components used in production of glucose test strips. Additionally since many billions of test strips are produced each year the manufacturability of the strip design and production process are important factors in device performance. Consistency of material properties such as hydrophilicity for test strip hydrophilic films and optimized features such as a precision cutting adhesive can improve device performance and help drive cost out of the products. Meeting device performance goals while looking for opportunities to take cost out of production are challenges all engineering teams face both with sustaining a product and new device system designs.

Accuracy of glucose test results is critical for a person living with diabetes. The glucose test strip is a critical component in managing a diabetics disease. If a device does not present results accurately, adverse clinical outcomes may result ranging from life threatening events to severe chronic complications.

The very small amounts of blood used in glucose test strips requires control via a technology called microfluidics – the science of moving microscopic volumes of fluids through tiny channels in a device. One way the device manufacturing industry is doing its part to improve device performance and innovate in microfluidics is using quality materials and manufacturing processes. Solventum's vast experience in coatings, films and surface modification technology is being applied to microfluidics to create films to precisely manage the flow of fluids in glucose test strips.

A recent study completed by The Diabetes Technology Society (DTS)¹ surveilled 18 different commercially available Blood Glucose Monitor Systems (BGMS) representing approximately 90% of the commercially available systems and tested them for accuracy. The results of the study indicated that of the blood glucose monitoring systems tested only 6 of the 18 products received the DTS Seal of Approval – 66% of the systems tested failed the criteria for Seal of Approval. Clearly all BGMS do not delivery the same level of performance as measured by this leading diabetes technical organization.

Quality materials

Design and production of quality materials begins with a team of experts. A strong team is built with people of unique skill sets; the varied backgrounds of experts from quality, clinical, laboratory and manufacturing should be the foundation from which your product is built.

Quality: These folks make sure the product requirements are understood and then translate them into specifications. It's also their job to set the project up for long-term success by ensuring product stability and repeatability testing is completed.

Clinical: The clinical team conducts testing to support material compatibility with your reagents and analytes. The test results are used to support confidence that the materials selected will be compatible for the intended use.

Laboratory: The lab team can also be thought of as the experimentation team. They may help you transition from your concepts to a fully-functional device that is ready to scale. They also typically provide input on technical documents necessary to support device registration and provide post market technical support.

Manufacturing: When your prototypes are ready for evaluation during commercialization and scale-up, the manufacturing team gets involved to make sure the correct equipment and processes are in place and the production process can deliver consistent materials.

Accuracy, consistency, and reliability of material properties are important factors to consider in selecting a material supplier partner. Device makers ask: do the materials perform the same lot-to-lot, are the materials critical to quality attributes such as coating thickness or uniformity adequate for my design? Do I have responsive support



and are my suppliers capable of providing technical and analytical assistance through the product life-cycle? Are the design criteria being supported with the selected materials consistently? Are the equipment and manufacturing processes capable to produce the product reliably? Does the manufacturing facility adhere to GMP standards? A development partner you can trust to deliver consistent materials and that you can rely upon to help solve design and process challenges is crucial to success.

Common test strip designs may incorporate several materials produced by Solventum specifically to address the needs of BGMS manufacturers. Typical among strip designs is the use of a transparent hydrophilic top film designed to wick or promote movement of the sample blood drop into a capillary test chamber. The test strip chamber is likely formed via lamination of one or more “spacer” layers that have been processed via a notch cutting operation. The bottom layer is usually a reagent pad deposited onto a conductive layer that contains various circuitry to allow electrochemical measurements. Solventum has decades of experience in the fields of coatings, adhesives, films, and metal deposition that are uniquely suited to address the needs of design teams and supply each component of test strip designs.

Inconsistent bonding between layers due to coating variability or coating defects may impede fluid flow of direct flow into unintended areas of the test strip causing device errors. At Solventum we leverage our vast experience to produce materials uniquely designed to meet the needs of diagnostic system design teams. Our technical specialists and unique process capabilities are leveraged daily by our customers to produce billions of test strips each year.

Hydrophilic or “water loving”?

Hydrophilicity is achieved by leveraging chemistry to change the surface energy of a surface. There are many ways to use coatings or surface treatments to modify the surface of a film. A primary factor to consider is how to leverage the knowledge of bio-chemistry to produce chemical reactions, hydrophilic polymers, and cellulose fibers that promote fluid flow without contaminating or interacting with biologic sample.

Beyond glucose test strips, hydrophilic films are now used in combination with adhesives to produce multi-layer “chips” to perform more complex diagnostic tests. The miniaturization of laboratory tests into small form factors is revolutionizing medicine by allowing sophisticated tests to be accomplished more quickly and closer to

patient. Lab-on-Chip (LOC) devices may require various film thickness and prefer coatings to be on one or both sides of the film. In some of these more advanced (LOC) device designs additional features may be required of materials such as combining hydrophilic surfaces with specialty light management attributes. Solventum expertise with display technologies positions us uniquely to supply films requiring specific optical properties such as: lensing, optical filtering, and absorbing or reflective surfaces. Solventum Medical Materials and Technologies can supply a range of standard solutions or more custom designs may be considered to meet your design criteria – speak with us about your needs.

Accurate and precise glucose monitoring doesn’t work unless your material supplier partner has the experience, competence, and controls required to deliver high quality consistent products to support your design needs. The glucose monitoring meter and test strip work together to measure and report the blood glucose concentration – letting the patient know if their glucose level is high, low or right on target. More importantly, accuracy and precision is critical when making decisions on lifestyle changes to react to the blood glucose levels.

References:

¹ Diabetes Technology Society (2018) Blood Glucose Monitoring System Surveillance Program, <https://www.diabetestechnology.org/surveillance.shtml>

Different ways to do hydrophilicity

A surface texture and chemical modification technique can be leveraged to enhance the wetting properties of a film surface.

In **Figure 1** 3M™

9984 hydrophilic film

has a micro-textured surface and a chemical modification that efficiently wicks a sample of blood into the strip’s test chamber, and the meter then senses the fluid and starts the measurement process. System design, material selection, and quality of materials all contribute to the performance and accuracy of the test result.

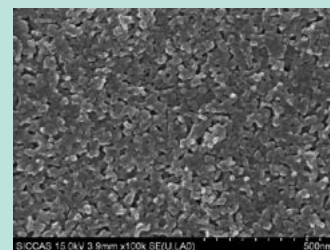


Figure 1

Tomorrow's advances—the ones you are developing today—will encourage diabetics to take on more ownership in their care. There is no doubt that affordability and consumer confidence will both play a key role in driving these advances. Solventum's expertise in materials and applications can help you make your next generation of diabetes monitoring solutions a reality through improving precision and accuracy without driving up costs.

Solventum hydrophilic films

Product attributes	9984 Diagnostic Hydrophilic Film	9962 Diagnostic Hydrophilic Film	9960 Diagnostic Hydrophilic Film
Hydrophilic technology	Surfactant-free	Surfactant-based	Surfactant-based
1-side coated or 2-sides coated	1-side coated	2-sides coated	2-sides coated
Thickness	3.9 mils (99 microns)	3.9 mils (99 microns)	6.8 mils (173 microns)
Base film	PET	PET	PET
Wet index	*	≥36	≥36
Contact angle	<20°	*	*
Total light transmission	≥90%	*	*
Light transmission (700nm)	*	92%	91%
Light transmission (400nm)	*	85%	85%
Heat shrinkage - machine & cross-web directions	≤0.7%	≤1.1%	≤1.3%
Break strength (Tensile) machine direction	≥85 lb/in	≥85 lb/in	≥131 lb/in
Break strength (Tensile) cross-web direction	≥103.7 lb/in	≥103.7 lb/in	≥163.0 lb/in
Break elongation machine direction	≥90%	≥90%	≥70%
Break elongation cross-web direction	≥60%	≥60%	≥47%
Non-toxic to mammalian cells	Yes	Yes	Yes
Non-hemolytic	Yes	Yes	Yes
Low autofluorescence	Yes	Yes	Yes
Shelf life	24 months	14 months	14 months
Go-to applications	Biosensors, test strips, lab-on-a-chip	Biosensors, test strips, Lab-on-a-chip	Biosensors, test strips, Lab-on-a-chip

*Data unavailable at the time of publication.

Visit go.Solventum.com/DiagnosticMaterials to learn more



Solventum MedTech OEM

Phone 1-800-742-1994
Web go.Solventum.com/MedTechOEM

©Solventum 2025. Solventum, the S logo and other trademarks are trademarks of Solventum or its affiliates.

1591435