APPLICATION NOTE

No. AN53373

Ensuring product safety and efficacy of alcohol-based hand sanitizers

Chapter three: Simplified software provides powerful new capabilities

The Centers for Disease Control and Prevention (CDC) first revised its hand hygiene guidelines in 2002 to recommend alcohol-based hand sanitizer as a possible alternative to hand cleansing with soap and water for the public and health care personnel.[1] The majority of alcohol-based hand sanitizers contain either isopropanol, ethanol, n-propanol, or a combination of two of these alcohols. The antimicrobial activity of alcohols can be attributed to their ability to denature proteins. The best antimicrobial efficacy can be achieved with ethanol (60 to 85%) and isopropanol (60 to 80%) solutions.[2] Higher concentrations are less potent because proteins are not denatured easily in the absence of water, whereas solutions with lower than 60% alcohol may only reduce the growth of germs but not kill them.

In response to the Coronavirus Disease (COVID-19) pandemic, the Food and Drug Administration (FDA) has recently issued guidelines[3,4] that temporarily allow compounders and certain entities that are not currently regulated by FDA as drug manufacturers to prepare and distribute hand sanitizer products for the duration of the public health emergency. Despite the relatively simple formulations and preparation protocols, it is critically important that proper quality assurance and control measures are in place to ensure the safety and efficacy of hand sanitizer products.

The Thermo Scientific™ Nicolet™ Summit FTIR Spectrometer is the perfect instrument for many material confirmation applications in different product areas. Tasks like confirming chemical composition of starting materials, verifying purity of intermediate steps, meeting regulatory requirements and verifying the final product can all be rapidly completed. In a previous application note,[5,6] we described how QA/QC workflows could be developed on the Nicolet Summit PRO FTIR Spectrometer with the Thermo Scientific™ Everest ATR accessory running the new Thermo Scientific™ OMNIC™ Paradigm Software. The OMNIC Paradigm Software provided with the Nicolet Summit FTIR Spectrometer has a new, powerful workflow developer capability that can create an application package containing all workflows required for a specific task. In this application note, we will describe the steps in creating a simplified application package for the analysis of hand sanitizer.

The final QA/QC package that the operator or analyst interacts with is a set of simple, push-button workflows (Figure 1).

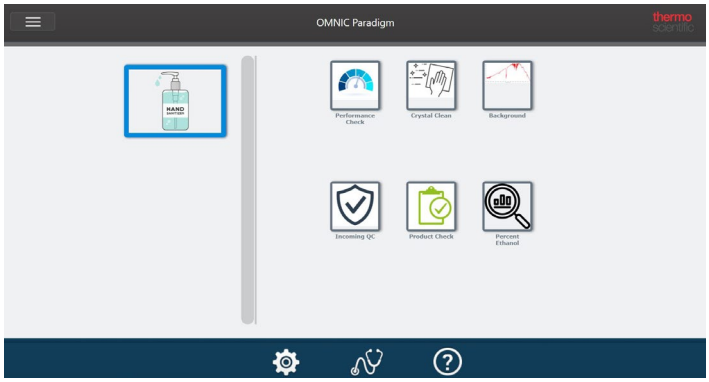

Figure 1: OMNIC Paradigm Operator Mode showing the workflows that are accessible from the analyst or operator.

ThermoFisher SCIENTIFIC

The top line of three workflows includes the initialization workflows or those that we recommend starting with before the sample analysis begins.

1. **Performance Check** measures the instrument noise, spectral quality, and other essential performance parameters of the FTIR spectrometer
2. **Crystal Clean** ensures the ATR crystal is properly cleaned before the analysis to minimize cross-contamination
3. **Background** measures the signal of the instrument with no sample present

The lower set of three workflows include the actual analysis workflows, which are used to measure the hand sanitizer production process:

1. **Incoming QC** checks to make sure the incoming material is the alcohol specified on the packaging
2. **Product Check** verifies the production lot has the same spectral fingerprint as an approved reference sample that meets all specifications. This also ensures that significant levels of methanol are not present in the final product.[7]
3. **Percent Ethanol** determines the percent ethanol in the final product to verify that it meets regulatory requirements

The workflows used in the package (i.e., the instructions, prompts, and pictures the operator sees when they click one of the icons) are customizable and easily created in the workflow editor mode of the OMNIC Paradigm Software. The image below shows the **Incoming QC** workflow (Figure 2). Users can easily modify the workflow with decisions, loops, images, and instructions.

Once the workflows for the application have been completed, users can create a package (Figure 3). A package may have multiple categories or just one, like we showed in Figure 1. Workflows are easily added to the package by selecting them from a file menu. Users can also select an image for each category for easy recognition of which workflows perform which task.

After a package has been created, it can be deployed to multiple instruments in Operator mode. When in Operator Mode, the user only sees the icons that were created in the packager. The user selects which workflow they want to run, follow the prompts, and immediately see results in <1 minute (Figure 4).

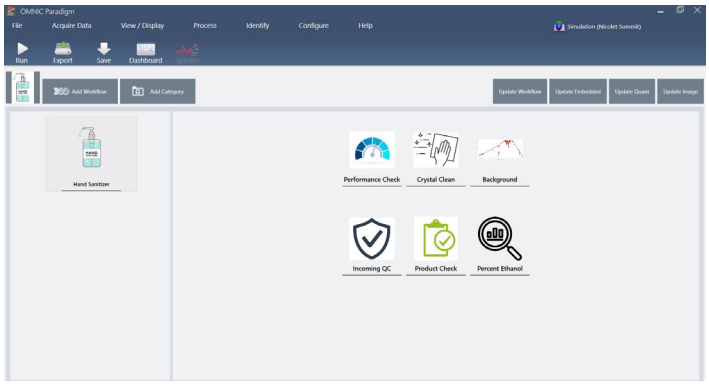

Figure 3: Package editor in the OMNIC Paradigm desktop software is used to create the user-interface seen by the analyst.

Figure 4: Example result from a workflow.

In summary, the new workflow packager within the OMNIC Paradigm Software creates a powerful tool for lab managers. With this new feature, users can easily create customizable workflow packages that can be used to bundle the workflow for a certain analysis type. The software can be configured so the end user or analyst can only access the workflow within a package, thereby providing maximum process control and ensuring repeatable results time after time.

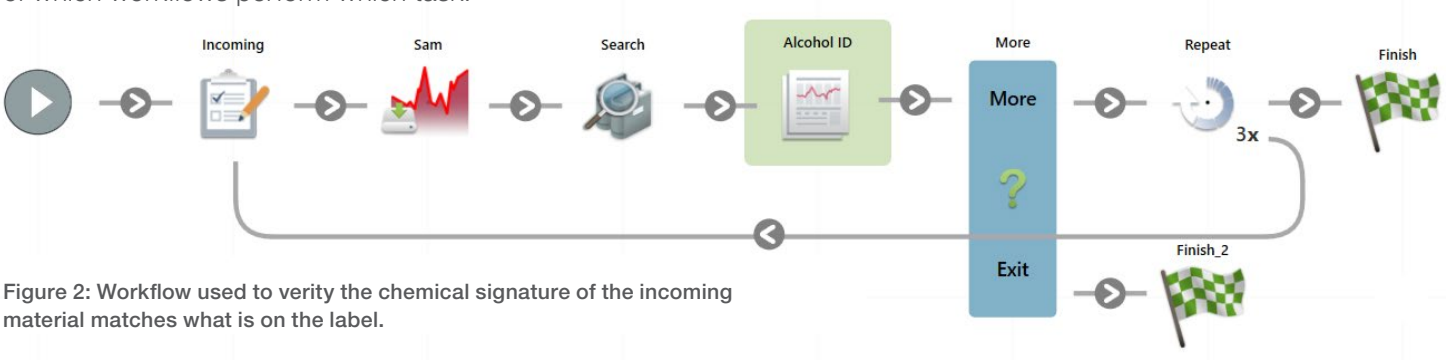

Figure 2: Workflow used to verity the chemical signature of the incoming material matches what is on the label.

thermo scientific

References

1. J.M. Boyce and D. Pittet, Guideline for Hand Hygiene in Health-Care Settings, Morb. Mortal. Wkly. Rep. 51:1-45, 2002
2. Kampf G, Kramer A. Epidemiologic background of hand hygiene and evaluation of the most important agents for scrubs and rubs. Clin Microbiol Rev. 2004 Oct; 17(4):863-93.
3. Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency, Immediately in Effect Guidance for Industry, https://www.fda.gov/media/136118/download
4. Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Healthy Emergency (COVID-19), Guidance for Industry, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-temporary-policy-preparation-certain-alcohol-based-hand-sanitizer-products-during
5. Sukumaran, S., Chen, R. (2020). Ensuring product safety and efficacy of alcohol-based hand sanitizers (Application Note: AN53310). https://assets.thermofisher.com/TFS-Assets/MSD/Application-Notes/AN53310-ensuring-product-safety-efficacy-alcohol-based-hand-sanitizers.pdf
6. Sukumaran, S., Chen, R. (2020). Ensuring product safety and efficacy of alcohol-based hand sanitizers Chapter two: In a production environment (Application Note: AN53344). https://assets.thermofisher.com/TFS-Assets/MSD/Application-Notes/AN53344-hand-sanitizer-efficacy-production-environment.pdf
7. FDA Updates on Hand Sanitizers with Methanol, https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-hand-sanitizers-methanol

Find out more at **thermofisher.com/summit**

ThermoFisher SCIENTIFIC