# Tracer Summit™

## Critical Control System

May 2004

BAS-PRC017-EN

# Introduction

## Life science—Addressing your needs

Trane is focused on understanding the imposing business challenges of life science companies. We understand the intense competitive pressures and the compressed time lines required to succeed in this highly regulated industry.

Increased enforcement efforts by the U.S. Food and Drug Administration (FDA) have compliance management, facility operations, and IT resources on alert. The massive costs of a compliance or validation shortcoming cannot be afforded. Trane is responding to these challenges with solutions that include mechanical equipment, compliance-enabled controls, and validation documentation templates.

Trane is designing solutions for facilities devoted to research, development, manufacturing, and product stability across the life science industry. Our integrated systems provide tightly controlled environments for pharmaceuticals, genome projects, medical devices, and a full range of biotechnology products.

## Trane—People, systems, and technology to give you a business advantage

Partnering with Trane can provide a measurable competitive advantage in the fast-paced world of life science. You benefit from maximum uptime, plus time savings, from the constant availability of all compliance data. Our strong relationships with the specialized firms capable of successfully designing and constructing life science facilities also help ensure the seamless success of this entire critical process.

As the only major HVAC *and* controls company, Trane can provide the standardized solution bundling and job coordination benefits that others cannot match. The integration of Trane HVAC equipment and controls, teamed with the corporate-engineering and validation expertise and the local support of the Trane organization, provides a single, valuable business partner for:

- Increasing speed to market—the most hotly pursued success factor in the life science industry
- Incorporating reliable building systems
- Reducing risk
- Saving installation and operational costs
- Managing regulatory compliance

## Tracer Summit Critical Control System

As part of Trane's Life Science Compliance Environment offering, the Tracer Summit building automation system provides complete building control through a single, integrated system. The Tracer Summit Critical Control System is an enhanced version of Tracer Summit that provides complete environment management for all FDA-regulated areas, from research to distribution.

This FDA-compliance-enabled control system is designed with extensive documentation and reporting capabilities to meet FDA 21 CFR Part 11. The Tracer Summit Critical Control System will keep your facilities aligned with FDA initiatives on "21st Century" practices, by providing:

- User security by authority level
- Audit trails for event and access tracing
- Display and reporting capabilities for critical environmental parameters

# Contents

# Features and benefits

## Pre-engineered applications

The Tracer Summit system has the most extensive library of pre-engineered environment-control applications in the industry. These applications, such as chiller-plant and variable-air-volume system control, bring an added level of reliability to potentially complex systems. Pre-engineered applications provide:

- Consistent solutions, independent of location, making systems easier to maintain and service
- Reduced risk of re-inventing solutions on a per project basis
- Solutions, engineered with Trane expertise, that are pre-tested in the factory for safe, reliable, and energy-efficient equipment and system operation
- Quick startup and checkout, minimizing installed costs

## Alarm management

With increasing amounts of valuable product and complex systems in today's life science facilities, system alarms can potentially be costly if the identification, troubleshooting, and resolution is difficult to accomplish. Considerations also must be made after the alarm occurs to prevent the abnormal condition from reappearing, including identifying the root cause and implementing corrective actions.

Also, the system's ability to route and display alarms must match the needs of the person or persons using the system. Tracer Summit Critical Control System has the flexibility and the robustness required to meet even the most proficient user's needs.

When an alarm occurs in the system, the program immediately routes the alarm according to the administrator-defined configuration. Configuration options include routing the alarm to a pager, printer, or any of the Tracer Summit workstations on the system. Alarms can also be sent by e-mail to any device that has the ability to receive e-mail messages, such as PCs, PDAs, mobile phones, and pagers. For additional flexibility, e-mail alarm routing can also be scheduled to send alarm messages to different e-mail addresses based on the day of the week or even the time of day.

After the alarm is received, the on-call system operator can utilize the many features of the Tracer Summit alarm log to troubleshoot the issue. The alarm log allows alarms to be easily accessed, acknowledged, or deleted by approved system operators. A series of filters can be used to show only the desired alarms, and critical alarms can be set up with custom messages and graphics to aid in alarm resolution.

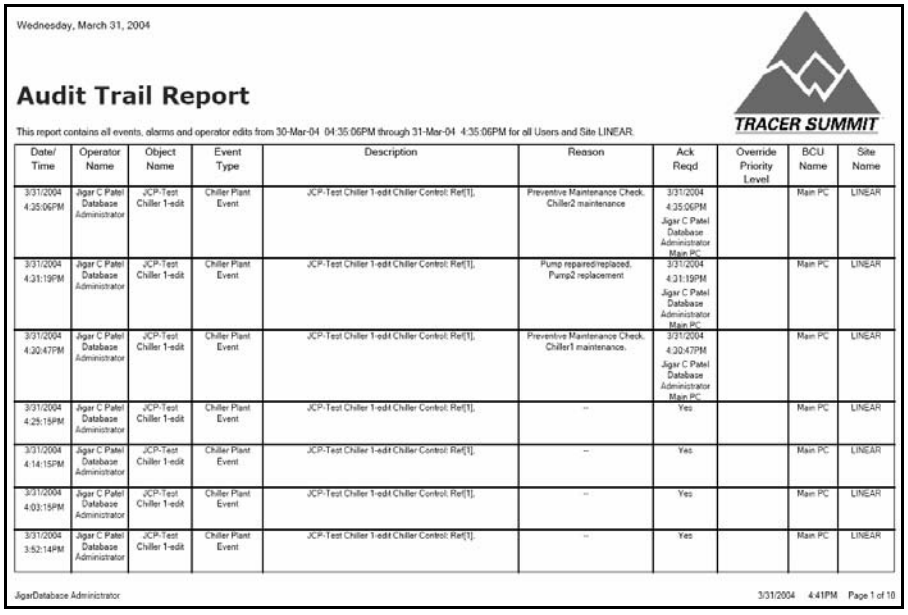
Alarm integrity is maintained throughout because all alarms are immediately captured in the secure audit trail upon generation. All user activities associated with alarms, such as acknowledgements and deletions, are also captured by the audit trail.

## Audit trail

The Tracer Summit Critical Control System provides a detailed, comprehensive audit trail to track system alarms and electronically signed operator activities. From a critical chiller alarm to a setpoint change, these electronic records are seamlessly stored in a secure data historian. Each entry in the audit trail includes a date and time stamp, operator name, object name, and a description of the alarm or activity. This information can be sorted by date/time, operator name, or by individual system objects, and a report can be displayed, exported, and printed (Figure 1).

With the ease of automatic capture and on-demand retrieval of data, the Tracer Summit audit trail is just the tool you need to ensure the long-term reliability and performance of your building systems, with the added result of expediting FDA system reviews.

**Figure 1. Audit Trail Report generated from Tracer Summit**



Wednesday, March 31, 2004

**Audit Trail Report**

TRACER SUMMIT

This report contains all events, alarms and operator edits from 30-Mar-04 04:35:06PM through 31-Mar-04 4:35:06PM for all Users and Site LINEAR.

| Date/ Time | Operator Name | Object Name | Event Type | Description | Reason | Ack Reqd | Override Priority Level | BCU Name | Site Name |
|---|---|---|---|---|---|---|---|---|---|
| 3/31/2004 4:35:06PM | Jigar C Patel Database Administrator | JCP-Test Chiller 1-edit | Chiller Plant Event | JCP-Test Chiller 1-edit Chiller Control: Ref[1]. | Preventive Maintenance Check, Chiller2 maintenance | 3/31/2004 4:35:06PM Jigar C Patel Database Administrator Main PC | | Main PC | LINEAR |
| 3/31/2004 4:31:19PM | Jigar C Patel Database Administrator | JCP-Test Chiller 1-edit | Chiller Plant Event | JCP-Test Chiller 1-edit Chiller Control: Ref[1]. | Pump repaired/replaced, Pump2 replacement | 3/31/2004 4:31:19PM Jigar C Patel Database Administrator Main PC | | Main PC | LINEAR |
| 3/31/2004 4:30:47PM | Jigar C Patel Database Administrator | JCP-Test Chiller 1-edit | Chiller Plant Event | JCP-Test Chiller 1-edit Chiller Control: Ref[1]. | Preventive Maintenance Check, Chiller1 maintenance. | 3/31/2004 4:30:47PM Jigar C Patel Database Administrator Main PC | | Main PC | LINEAR |
| 3/31/2004 4:29:15PM | Jigar C Patel Database Administrator | JCP-Test Chiller 1-edit | Chiller Plant Event | JCP-Test Chiller 1-edit Chiller Control: Ref[1]. | -- | Yes | | Main PC | LINEAR |
| 3/31/2004 4:14:15PM | Jigar C Patel Database Administrator | JCP-Test Chiller 1-edit | Chiller Plant Event | JCP-Test Chiller 1-edit Chiller Control: Ref[1]. | -- | Yes | | Main PC | LINEAR |
| 3/31/2004 4:03:15PM | Jigar C Patel Database Administrator | JCP-Test Chiller 1-edit | Chiller Plant Event | JCP-Test Chiller 1-edit Chiller Control: Ref[1]. | -- | Yes | | Main PC | LINEAR |
| 3/31/2004 3:52:14PM | Jigar C Patel Database Administrator | JCP-Test Chiller 1-edit | Chiller Plant Event | JCP-Test Chiller 1-edit Chiller Control: Ref[1]. | -- | Yes | | Main PC | LINEAR |

JigarDatabase Administrator 3/31/2004 4:41PM Page 1 of 18

## System security

Preventing unauthorized access is a basic, but very important, function of any building automation system. The value of the systems and data utilized by the life science companies makes security an issue of critical importance. The security model offered by the Tracer Summit Critical Control System is comprehensive and can be customized for each user (Figure 2). Security features include:

- Unique, confidential, user-defined passwords
- Password aging
- User lockout after multiple unsuccessful log-in attempts
- Inactivity timeouts
- User archiving
- Change-description and sign-off requirements for system configuration changes and alarm acknowledgements

Access for each individual user can be controlled by system function, application, and object type. This allows restrictions based on user qualifications, such as training, or on responsibilities, such as building area.

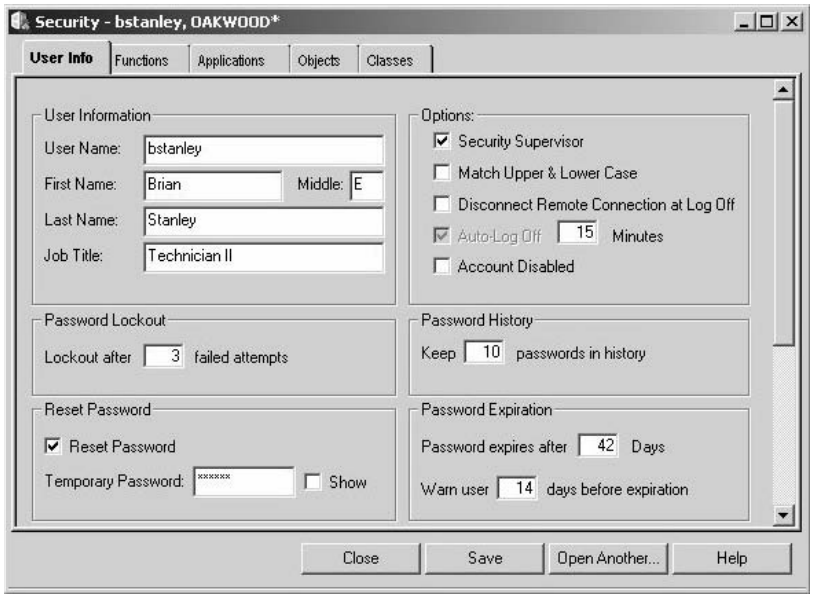
## System and data integrity

Unauthorized user access is not the only threat to critical systems. Technical issues can also put your systems at risk if the appropriate precautions are not taken to increase system and data integrity.

With all of the time, effort, and expense of validating the system and logging critical system data, keeping critical system components and data in a secure location is a must.

Trane understands the importance of these assets to your business and has engineered a data historian using Microsoft SQL Server technology. This historian maintains the integrity of all system-critical data, including audit trail data, in a central location. System backup and data-archiving utilities are also included to protect your investment.

**Figure 2. Security setup in Tracer Summit**



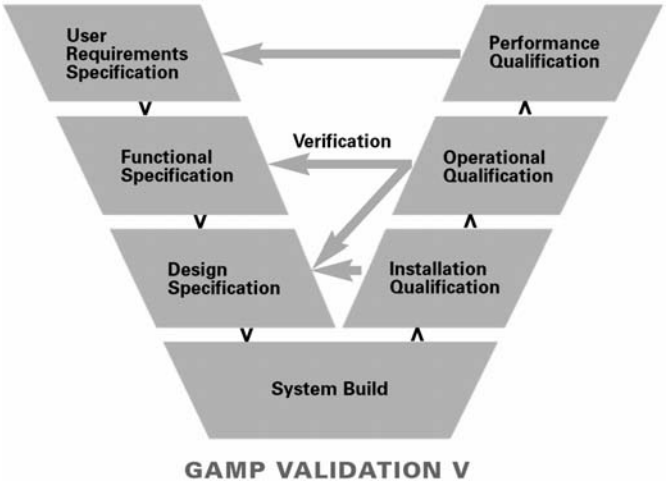

## Compliance documentation and consulting

A key element of the validation process is having complete and detailed documentation (Figure 3). The high importance of the documentation is reflected in the potentially high cost of generating it. The Tracer Summit Critical Control System comes with a complete set of standard documentation templates. These templates can shorten the preparation time for and reduce the cost of validation. Template documents include:

- Validation Master Plan (VMP)
- User Requirements Specification (URS)
- Functional Specification (FS)
- Design Specification (DS)
- Installation Qualification (IQ)
- Operation Qualification (OQ)
- Performance Qualification (PQ)

Consulting services are also available from experienced staff at Trane and through any of our independent validation industry partners.

**Figure 3. Validation process documentation**



## Reports and trends

Viewing current, as well as previous, system operations provides invaluable information for optimal system operation and troubleshooting. The Tracer Summit reporting and trending capabilities provide this ability.

For example, calculating and monitoring the mean kinetic temperature (MKT) is required by good warehousing and distribution practices when storing perishable goods, such as pharmaceuticals. The Tracer Summit MKT standard report allows life science customers to easily calculate this parameter over a user-defined time period (Figure 4).

Tracer Summit has a large library of other standard reports as well, including those for each piece of Trane equipment, which provides a valuable source of record-keeping and troubleshooting data. Custom reports can also be defined for any desired values in the system, including such data as energy usage or run-time reporting.

The Tracer Summit trending capabilities can produce a broad variety of sample data at regular intervals, as well as real-time data. Critical data can be earmarked for inclusion in the audit trail database to maintain integrity for FDA review. Trend data can be viewed on the screen, printed, or saved to a file. A graphical representation of real-time data is also available using custom graphics.

## System integration

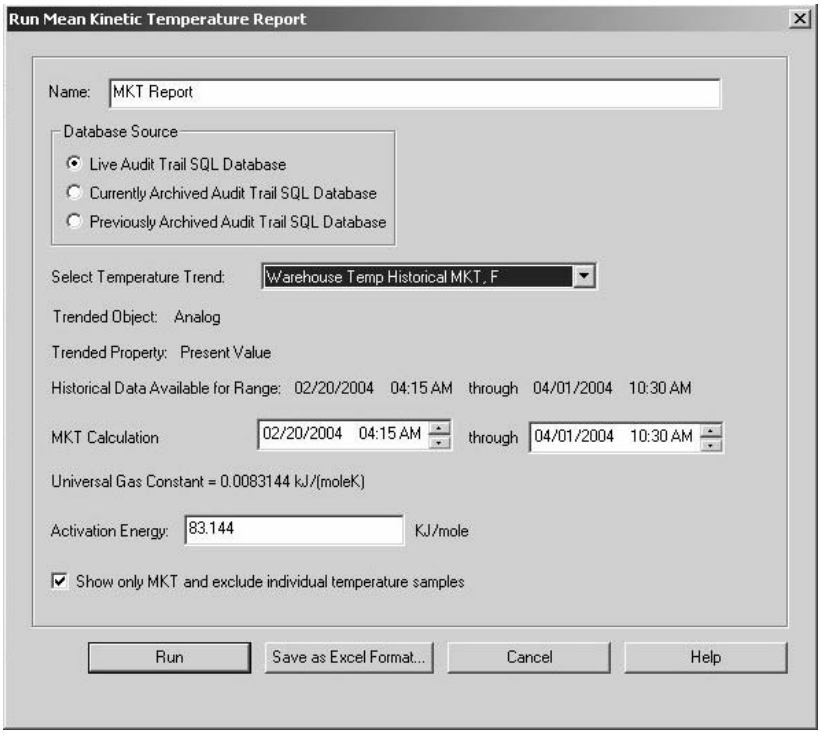
Integrating devices and building subsystems can provide several benefits to all building owners, including those in the life science industry. Not only can integration provide cost savings through single-seat operation, but it can also help to reduce risk. The Tracer Summit system can become an integration platform using the open standard protocols of BACnet, LonTalk®, and Modbus Remote Terminal Unit (RTU).

The following is a list of a few of the many types of equipment and systems that will integrate into the Tracer Summit system:

- HVAC systems
- Lighting control
- Laboratory systems—fume hood and room pressurization control
- Security and access management
- Fire and life safety
- Computerized maintenance management systems
- Industrial process control—PLCs and SCADA systems
- Energy systems—Energy-usage monitoring and UPS systems

For each application, Trane selects a variety of vendors to develop and test interfaces to. These interfaces allow flexibility when selecting the initial systems or vendors to work with and assures competitive bidding for system additions and modifications.

**Figure 4. Mean Kinetic Temperature Report setup**




## The Trane advantage

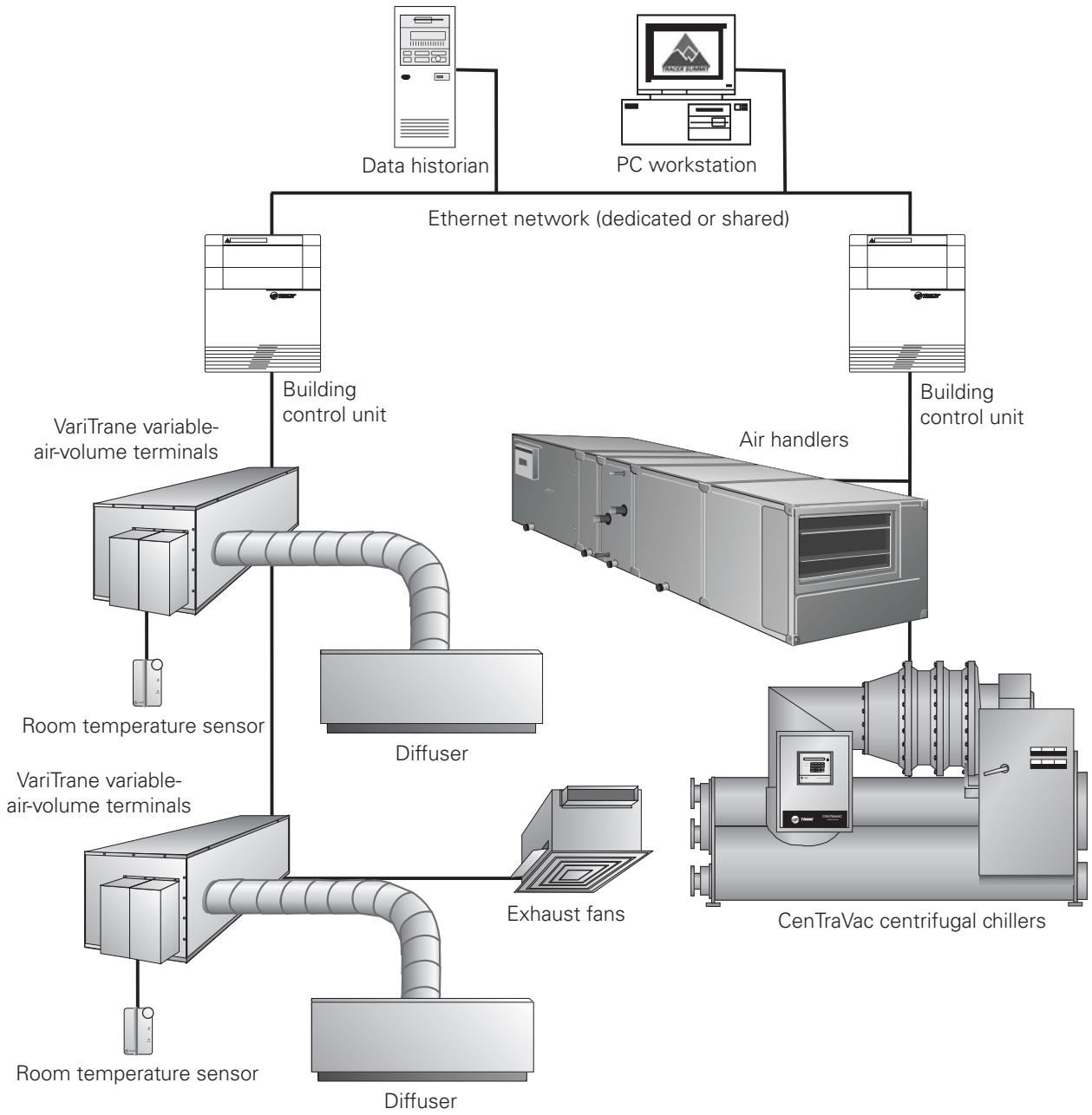
The Life Science Compliance Environment offering consisting of Tracer controls, Trane HVAC equipment with integrated controls, along with Trane's contracting, engineering, application, service, and validation expertise can provide unmatched, single-source solutions.

For more information on comprehensive, FDA-compliance enabled systems for life science facilities, contact your Trane account manager or local Trane office today.

# System architecture

The Tracer Summit system architecture is highly distributed (Figure 5). Control can occur at the appropriate system level to ensure integrity.

**Figure 5. Typical example of Tracer Summit Critical Control System architecture**



# Specifications

## System

FDA 21 CFR Part 11 compliant when installed and validated in a manner consistent with industry practices

## PC Workstation

### Hardware requirements

Tracer Summit Critical Control System must have the following:

- 1 GHz processor
- 512 MB RAM
- 20 GB hard drive storage
- 32X CD-ROM drive
- 15-inch super video graphics adaptor (SVGA) monitor, 16-bit color, 800 × 600 resolution (1024 × 768 or higher recommended)
- Keyboard and mouse
- Parallel port for printer (optional)
- 16-bit sound card with speakers
- Windows XP Professional operating system
- Internet Explorer Version 5 or higher
- Microsoft Data Access Components (MDAC) Version 2.8 or higher
- One PCI or ISA slot for an Ethernet network adapter

### Optional hardware

- Additional memory and disk capacity
- Parallel printer
- System backup hardware (such as a tape drive or CD-RW drive)
- UPS recommended

### Software

The installation CD includes:

- Workstation software
- Library of graphic images and routines
- Documentation for the installer, daily user, and programmer

## Data historian

A server must be supplied for use as a data historian. Assuming that the server will be used for Tracer Summit Critical Control System use only, the hardware selection must meet the following minimum requirements:

- Windows 2000 or Windows 2003 Server
- Windows SQL 2000 (standard or Enterprise) database
- 1 GHz processor with a 512 K cache
- 1 GB RAM
- 2 quantity 36 GB SCSI hard drives
- RAID1 Parity System
- UPS recommended

## Building control unit

### Power requirements

Nominal rating
120/240 Vac; 50 or 60 Hz; 1 pH

Voltage utilization range
120 Vac, nominal: From 98 to 132 Vac
240 Vac, nominal: From 196 to 264 Vac

Maximum current
6.0 A at 120 Vac dedicated circuit breaker

### Operating environment

Temperature
From 32°F to 120°F (0°C to 50°C)

Relative humidity
From 10% to 90%, non-condensing

### Storage environment

Temperature
From -50°F to 150°F (-46°C to 66°C)

Relative humidity
From 10% to 90%, non-condensing

### Enclosure

NEMA-1

### Dimensions

19 in. high × 16 in. wide × 6 in. long
(482 mm × 406 mm × 152 mm)

### Weight

20 lb (9.1 kg) shipping
15 lb (6.8 kg) net (hanging)

### Mounting

Wall-mounted with ¼ in. hardware

### Clearances (recommended minimum)

- 12 in. (30 cm) at top, bottom, and sides
- 36 in. (91 cm) in front
- 46 in. (1.2 m) above floor (for wall-mounted BCU)

### UL listing

- UL-916-PAZX—energy management
- CUL-C22.2—energy management—Canada

### FCC

FCC part 15, Class A

### CE

- Emissions: EN55022 Class B
- Immunity: EN50082-2:1995 Industrial
- Safety: EN61010-1 A2:1995

### Memory

Standard capacity
FLASH: 2 MB
EEPROM: 256 KB
RAM: 1 MB

High capacity
FLASH: 4 MB
EEPROM: 516 KB
RAM: 2 MB

### Battery

No battery is required. The clock is maintained for a minimum of three days by the super capacitor. All other programs are backed up by nonvolatile memory.

### BACnet communications

Tracer Summit communicates to devices that support:

- Communication based on the BACnet ASHRAE/ANSI 135 standard
- ENV-1805-1/ENV-13321-1
- 10 Base-T dedicated Ethernet (ISO/IEC 8802-3) or Transmission Control Protocol/Internet Protocol (TCP/IP) compatible network

### LonTalk® communications

Tracer Summit communicates to devices that support:

- Communication based on the EIA-709.1 (LonTalk®) standard
- LonTalk® standard network variable types (SNVTs)
- FTT-10A transceivers
- Twisted-pair physical media

### Modbus communications

Tracer Summit communicates to devices that support the Modbus Remote Terminal Unit (RTU) protocol using the Tracer Summit communications bridge.

# BACnet PICS—BCU

## Basic information

| | |
|---|---|
| Vendor name | Trane |
| Product name | Tracer Summit BCU |
| Product description | Tracer Summit Building Control Unit |

## BACnet standard application services supported

| Application service | Initiate | Execute |
|---|---|---|
| CreateObject | × | × |
| DeleteObject | × | × |
| ReadProperty | × | × |
| ReadPropertyMultiple | × | × |
| WriteProperty | × | × |
| WritePropertyMultiple | × | × |
| ConfirmedPrivateTransfer | × | × |
| UnConfirmedPrivateTransfer | × | × |
| ReinitializeDevice | | × |
| TimeSynchronization | × | × |
| Who-Has | | × |
| I-Have | × | |
| Who-Is | × | × |
| I-Am | × | × |

## Standard object types supported

| Object types | Support |
|---|---|
| Analog input | Creatable Deletable |
| Analog output | Creatable Deletable |
| Binary input | Creatable Deletable |
| Binary output | Creatable Deletable |
| Device | Supported |

## Data link layer

| |
|---|
| BACnet/IP (Annex J) |
| Ethernet (ISO/IEC 8802.3), 10-BASE-2 |
| Ethernet (ISO/IEC 8802.3), 10-BASE-T |
| Ethernet (ISO/IEC 8802.3), 10-BASE-FL |
| ARCNET, coax bus |
| ARCNET, fiber star |
| ARCNET, coax star |
| Point to point, EIA-232 |

## Special functions

| | |
|---|---|
| Maximum APDU size in octets | 474 |
| Segmented requests supported, window size | 1 |
| Segmented responses supported, window size | 1 |

## Character sets supported

| |
|---|
| ANSI, X3.4 |

# BACnet PICS—PC Workstation

## Basic information

| | |
|---|---|
| Vendor name | Trane |
| Product name | Tracer Summit PC Workstation |
| Product description | Tracer Summit PC Workstation |

## BACnet standard application services supported

| Application service | Initiate | Execute |
|---|---|---|
| CreateObject | × | |
| DeleteObject | × | |
| ReadProperty | × | |
| ReadProperty Multiple | × | |
| WriteProperty | × | |
| WriteProperty Multiple | × | |
| ConfirmedPrivate Transfer | × | × |
| UnConfirmed PrivateTransfer | × | × |
| ReinitializeDevice | × | |
| Time Synchronization | × | |
| Who-Is | × | × |
| I-Am | × | × |

## Standard object types supported

| Object types | Support |
|---|---|
| Device | Supported |

## Data link layer

| |
|---|
| BACnet/IP (Annex J) |
| Ethernet (ISO/IEC 8802.3), 10-BASE-2 |
| Ethernet (ISO/IEC 8802.3), 10-BASE-T |
| Ethernet (ISO/IEC 8802.3), 10-BASE-FL |
| ARCNET, coax bus |
| ARCNET, fiber star |
| ARCNET, coax star |
| Point to point, EIA-232 |

## Special functions

| | |
|---|---|
| Maximum APDU size in octets | 474 |
| Segmented requests supported, window size | 1 |
| Segmented responses supported, window size | 1 |

## Character sets supported

| |
|---|
| ANSI, X3.4 |





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| | |
|---|---|
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